Open Source

Biotechnology

Janet Elizabeth Hope

A thesis submitted for the degree of
Doctor of Philosophy at
The Australian National University

April 2005

This thesis is an account of research undertaken in the Research School of Social Sciences and the Faculty of Law at the Australian National University between February 2001 and December 2004.

This research was supervised by Professor Peter Drahos, but unless otherwise indicated, the work presented herein is my own.

None of the work presented here has ever been submitted for any degree at this or any other institution of learning.

Janet Elizabeth Hope
22 April 2005

Acknowledgements

It is a pleasure to thank the many people who made this research possible:

Professor Peter Drahos. I could not have hoped for a better or more understanding supervisor.

Professor Andrew Christie, Director, Intellectual Property Research Institute of Australia, for generous financial support and the opportunity to be part of a dynamic research environment outside my home institution.

My informants, for being willing to share ideas with a stranger in the spirit of scientific exchange. Some meetings lasted only five minutes between conference sessions, others lasted several hours, but all were useful in one way or another. I am particularly grateful to those informants who went out of their way to accommodate my travel schedule or time zone differences.

My informants' administrative assistants, many of whom went beyond the call of duty to help find gaps in their principals' busy schedules, good quality discount accommodation, transport information, and Internet access. Special thanks to Wendy Deaner and Carla Childers at UT Southwestern.

Roger Brent, Dawn Warfield and Lauren Ha at the Molecular Sciences Institute, for hosting and helping to organise the first ever Open Source Biology workshop, and for allowing me to share their facilities during the first two weeks of my visit to the United States. Thanks also to all who attended the workshop.

Brian Wright, Sara Boettinger and Greg Graff, for encouragement and advice.

Professor Jerry Reichman of Duke Law School, for encouraging me to continue my investigations, for subsidising my attendance at the April 2003 TRIPS conference and for making me welcome in his home along with other much more distinguished guests. Jennifer Jenkins and Lynn Martin, for their gracious hospitality despite the short notice.

The people at CAMBIA, for extraordinary creativity, openness and enthusiasm, especially Andrzej Kilian, Eric Huttner, Carolina Roa-Rodriguez, Carol Nottenburg and Richard Jefferson.

Dr Dianne Nicol and Jane Nielsen at the University of Tasmania, for intellectual fellowship and emotional support. Professor Don Chalmers, for flying me down to visit and treating me to what *looked* like a wonderful Christmas lunch.

Professor Larry Lessig, Glenn Otis Brown, Neeru Paharia and Laura Lynch at Creative Commons, and the students of Professor Lessig's Advanced Contracts seminar at Stanford Law School, for allowing me to witness the inner workings of the Creative Commons initiative. Special thanks to Neeru and Laura for driving me between Berkeley and Stanford.

Douglas Bock, Lizzy Wenk and Laura Grego, for very generous hospitality in Berkeley and Cambridge. Nigel Snoad, for putting me up in Manhattan and

welcoming me to New York by proxy. Amy Simpson, for being such a fine proxy.

The organisers of the 2003 Genetics Congress in Melbourne, for waiving the substantial attendance fee on the condition that I rough it with the journalists. The journalists, for showing me where to find the coffee, the computers and the free food.

Ms Judy Jones, acting supervisor in the early months of my candidature, without whom the transition from extended disability leave to full-time study would have been much slower and more painful. Professor Phillipa Weeks, Trevor Allen of the ANU Disability Support Unit, and the IT and administrative staff at the Law School, for the same reason.

Matt Rimmer, for ideas and inspiration. Chris Drew, for taking an interest. Both Matt and Chris, for keeping me in touch with cyberspace doings.

Madeleine Schultz, Chris Drew, John Kilcullen, Joe Hope, and Anne Kilcullen, for substantial and extraordinarily well-timed clerical assistance.

All my colleagues and friends at the Law School, Research School of Social Sciences Law Program, and RegNet, for practical help, encouragement, intellectual stimulation and good company. Zoe Pearson and Sophie Cartwright, for showing how it's done.

My friends, near and far, old and new, and my extended family, for enormous patience, encouragement and understanding in hard times, despite troubles of their own. Trish, Kate, Beck, Belinda, Bec, Judy, Nicky and Lisa for helping me start out as a mum with minimum fuss.

My parents, for – among so many other things – shielding me from many of the demands of new motherhood to allow me to complete this task. My husband, the roots of my heart; my lovely little buddy; my sister, who remembers what I remember.

The fieldwork underpinning this thesis was funded by the Intellectual Property Research Institute of Australia and by the Law Program, Research School of Social Sciences, Australian National University.

This thesis is dedicated to the stranger from China who approached me on campus in the last month of my pregnancy and told me I was an excellent woman, to bring a baby *and* study. May she live a long and extremely happy life.

Abstract

Dramatic recent expansion of intellectual property protection in the field of biotechnology has led to concerns that ongoing innovation will be blocked unless action is taken to preserve access to and freedom to operate with those tools that are important for further research and development.

The "open source" approach to technology licensing, development and commercialisation evolved out of the free software movement, initiated in the early 1980s in response to restrictive copyright licensing practices adopted by commercial software developers. This approach offers a means of reconciling the public interest in broad access to software development tools with the economic self interest of intellectual property owners.

Building on discussions with public and private sector industry participants, funding agencies, leaders of the free and open source software movement and scholars in a range of disciplines, this thesis assesses the desirability and feasibility of extending open source principles to biotechnology research and development. It argues that "open source biotechnology" is both desirable and broadly feasible, and demonstrates that many of the essential elements of an embryonic open source movement are already present in this field.

Contents

Chapter 1

Introduction

The idea for this thesis occurred to me in early 2002. At the time I was writing a history of biotechnology regulation in New Zealand, where a Royal Commission on Genetic Modification – the first public inquiry of its kind anywhere in the world – had recently completed its report.[1] The prospect of the first environmental release of genetically modified organisms had become a major issue in New Zealand's national elections, and in time-honoured fashion, proponents of commercial field trials were doing their best to label the public's opposition to genetically modified agriculture as irrational and ill-informed. A closer look had convinced me it was neither. The companies whose field trial applications were waiting in the wings were large North American and European firms seeking to shorten product development times by exploiting the southern hemisphere growing season; any profits the field trials might ultimately generate were unlikely to stay in New Zealand. Meanwhile, there was a possibility that the environmental release of genetically modified organisms would harm New Zealand's economically valuable reputation as a "clean green" holiday destination and producer of high quality food exports for northern hemisphere consumer markets, in which resistance to genetically modified products was rapidly increasing. As a remote island nation whose heavily agriculture-dependent economy included a strong and growing organic sector, New Zealand could make a unique and potentially lucrative claim to be truly "GM-free". Leaving aside questions about the inherent safety of the technology and the morality of tinkering with the molecule that scientists themselves had dubbed "the secret of life", many New Zealanders did not see why they should tolerate such a – literally incalculable – risk to their economic future for the sake of a small and uncertain share in the profits of overseas corporations.

Indigenous landowners' reactions to commercial field trial applications in New Zealand were particularly instructive. The better informed local Maori became, the more likely they were to oppose such applications, but although this opposition was generally expressed in terms of a clash between scientific objectives and Maori spiritual values, Maori were often surprisingly pragmatic in their dealings with commercial applicants. This pragmatism was seen by many as hypocrisy; to me it simply reflected the fact that, for Maori (whose spirituality centres around

[1] Royal Commission on Genetic Modification (2001).

responsible stewardship of New Zealand's genetic heritage) as for the rest of the community, what mattered most was not the technology itself but the purposes for which it was used, by whom, at whose risk, for whose benefit, and at whose behest.

As I grappled with the implications of commercial influence on the direction and applications of biotechnology research, my physicist husband recommended a book to read during coffee breaks: Sam Williams' free (as in beer)[2] online biography of Richard Stallman.[3] Struck by the parallels between Williams' account of the increasingly proprietary culture of software engineering during the late 1970s and early 1980s and the effects of the commercial biotechnology revolution on university-based life sciences research during the same period, I wondered what might happen if Stallman's simple but creative solution – copyleft licensing – were applied in biotechnology.[4]

A quick Google search revealed that I wasn't the first person to have this idea. The previous year, physicist Rob Carlson had written an essay entitled "Open Source Biology and its Impact on Industry"; the essay was linked to the Molecular Sciences Institute (MSI), a non-profit research organisation headed up by Nobel Prize-winning geneticist Sydney Brenner.[5] The MSI homepage included the following question and answer:

> What is open source biology? MSI is committed to making its research and its technology available to benefit the public. To this end, MSI publishes its scientific results in the open literature, makes reagents and methods freely available to the research community, and posts unpublished data on the web. MSI also distributes its software under Open Source licensing arrangements. Researchers at the MSI have been working with other institutions, scientists, engineers and legal experts to develop the concept of "Open Source Biology". If viable "Open Source" licensing schemes for biological methods and reagents can be developed, the Institute intends to use these schemes... to satisfy the criterion that the new technologies are disseminated for maximum public benefit.[6]

Subsequent investigations turned up other groups of scientists interested in applying open source principles to biotechnology research. For example, in 1999, a professor at Ontario Agricultural College had formulated a draft "GPL for Plant Germplasm";[7] a year or so later, human genome project researchers at Britain's Sanger Centre had briefly toyed with releasing sequence data under a copyleft-style licence.[8] Non-scientists were also thinking along similar lines: in April 2001,

[2]See below, p.68.
[3]Williams (2002).
[4]See below, p.68.
[5]Carlson (2001).
[6]The Molecular Sciences Institute (2004).
[7]McNaughton (1999).
[8]John Sulston, personal communication.

law professor Dan Burk presented a paper on "open source genomics" at a Symposium on Bioinformatics and Intellectual Property Law hosted by Boston University.[9] Three and a half years on, references to open source biotechnology and its variants crop up with increasing frequency at conferences, in journals and magazines, on the Internet and in successful funding applications. It seems that open source biotechnology was an idea whose time had come.

One part of the explanation for this spate of "parallel invention" may be the increasing involvement of researchers with hard science backgrounds – engineers, computer scientists and physicists – in biological research. The advent of the genomics era created a demand for people with new skills to manage and interpret large data sets. These new biologists have brought with them the philosophy and terminology of free and open source software development, just as the physicists who helped to found the discipline of molecular biology in the 1930s brought with them a revolutionary commitment to methodological reductionism.[10] On this view, it is no coincidence that bioinformatics research tools are predominantly open source. Another factor is the growing prominence of open source software itself – evidenced, for example, by a 2001 report for the United States Department of Defence demonstrating the applicability of Linux to the military business case.[11] But the ultimate cause of scientists' and others' reaching for an open source approach to biotechnology research and development is a growing sense of frustration with the failure of both the technology and the industry that has grown up around it to live up to its hype. Consumers are frustrated at being expected to buy unfamiliar products that do not seem to offer any direct benefit even in terms of price, and corporations are frustrated at consumer reluctance to accept genetic modification as a normal part of product development. Entrepreneurs, investors and science policy-makers are frustrated that the biotechnology industry has turned out not to be as profitable as everyone had hoped. International aid agencies are frustrated at the failure of a potentially cheap and powerful new technology to deliver on its early promise as the driver of a much-needed follow-on to the Green Revolution in agriculture or the source of new treatments for killer diseases like HIV/AIDS, tuberculosis and malaria. Finally, there is the day-to-day frustration of scientists who find themselves constrained by red tape as they attempt to exchange resources that are essential to major projects. This in itself is nothing new, and various manifestations of the problem have in fact been effectively resolved; but the understanding is beginning to dawn that from now on scientists may have to struggle to maintain access to every important resource, even – in fact, especially – those that are inherently non-substitutable. Researchers are realising with dismay that if it isn't ESTs, or sequence data, or SNPs, it will be the next tool, and the next.[12] The attraction of open source is

[9] Burk (2002).

[10] Regal (1996).

[11] Kenwood (2001).

[12] SNPs: Single Nucelotide Polymorphisms. ESTs: Expressed Sequence Tags. Both have been the subject of controversy in relation to proprietary claims: the National Institutes of Health's 1991 patent application on ESTs (partial cDNA sequences), though eventually withdrawn, sparked on-

that, as described in subsequent chapters, it appears to offer at least a partial solution to all of these problems – not as a replacement for other strategies, but as an option that may be taken up by individual players irrespective of the success or failure of other attempted solutions.

The obvious objection to open source biotechnology is that licensing and development principles that evolved in relation to software development may not be applicable in the biotechnology industry. Not only is software code itself quite different from a knockout mouse (say) or a method for inserting foreign genetic material into living cells, but there are other differences between software and biotechnology that could block the implementation of open source principles in the latter field: for example, compared with software development, the capital costs of development in biotechnology are higher, the prevailing industry culture is more proprietary, and innovations are typically protected under different legal regimes.[13]

With these potential obstacles in mind, I set myself the task of exploring the limits of the open source analogy in biotechnology. I chose to frame my research in terms of an analogy with "open source" rather than "free" software because the open source emphasis on appealing to innovators' economic self-interest, as distinct from their social conscience, addresses an important problem in biotechnology research and development. As sociologists of science have repeatedly demonstrated, scientists are not specially unbiased, altruistic or co-operative creatures, and their dealings with one another, like all human interactions, are often characterised by fierce controversy, ruthless competition, personal animosity, greed and dishonesty.[14] Nevertheless, the desire to serve the public interest – to do good by inventing useful technologies – is, at least in my personal experience, a strong motivating factor for many scientists. The difficulty is that shifts in patterns and sources of funding for scientific research have left scientists without a vehicle for making their technology freely accessible to users while simultaneously meeting the costs of development. The best option in many cases, despite its disadvantages, is for technology owners to follow one version or another of the proprietary business model, in which access to the technology is legally restricted in order to make it saleable by imbuing it with excludability, a characteristic of private goods. The open source approach offers a way of reconciling the public interest in minimising restrictions on access to new biotechnologies with the need of many innovators for economic self-sufficiency;[15] thus, the commercial applicability of open source is an important part of its appeal in this context.

The methods I used to carry out this research were essentially those of an

going debate about access to DNA sequence information and other materials, information and techniques needed to enable scientists to conduct cutting-edge research: National Research Council (1997).

[13]See section 5.2, p.96.

[14]See section 2.4, p.13.

[15]Open source licensing as a revenue-generating strategy is introduced in section 4.3.3, p.75, and discussed in more detail in chapter 7.

investigative journalist. Working largely from informal "hacker" writings published on the Internet, I identified a range of business strategies compatible with an open source approach to intellectual property management (see chapter 4). Using web addresses published by the Biotechnology Industry Organisation and regional business associations in the United States, I searched the business development pages of innovative technology companies, looking for conditions that might favour the application of open source principles: actual or potential sources of revenue, apart from licensing income, that might be boosted if a company's key technology were to become more widely used, as well as the potential for companies to reduce the cost of technologies that they used in-house by sharing research and development with other users. I wrote to the executive officers of companies in different technology areas requesting the opportunity to discuss alternative business models; the aim was to learn whether it would be feasible to implement open source strategies in those areas or, if not, to discover which aspects of the open source approach were considered unworkable. At the same time I contacted representatives of other institutions from different sectors of the biotechnology industry, including universities (both techology transfer offices and academic departments), private non-profit research institutions, large agribusiness and pharmaceutical companies and research hospitals; scholars in the fields of law, economics, sociology of science and innovation management; leaders of the free and open source software movement and their attorneys; program directors of major philanthropic organisations; the secretariat of the Consultative Group on International Agricultural Research; instigators and leaders of existing collaborative research programs in biotechnology; venture capitalists with investment experience in both biotechnology and open source software; and a handful of other people including freelance journalists who had published on open source biotechnology or related topics. In each case I sent a fax or email requesting a personal meeting or telephone discussion; to increase the chances that my letters would be read by their busy recipients, I kept each letter short, referring the reader to an Internet site hosted by the Australian National University (which I established for the purpose in January 2003) that contained a detailed description of the project.[16] My intention was not to conduct any kind of formal empirical study, but to complement an investigation based primarily on documentary analysis with insights drawn from the direct experience of a broad range of informants. For this reason I did not request written consent to participate in the study from interviewees or their employers; nor did I seek to establish a representative sample of participants from any particular industry sector. Although some of my messages went unanswered, I did manage to meet with a substantial number of informants, most of them during a six week field trip to the United States in March and April 2003 funded by the Intellectual Property Research Institute of Australia;[17] some meetings generated further contacts, as did the Internet site. Before leaving for the United States I also committed to or-

[16]Open Source Biotechnology Project website, http://rsss.anu.edu.au/ janeth.

[17]See http://www.ipria.org/.

ganising a half-day workshop on Open Source Biology to be hosted by the MSI in Berkeley, California, during the second week of my visit. Before and after the United States trip I conducted telephone interviews with informants in the United Kingdom and Ireland and on a number of occasions visited the Centre for Application of Molecular Biology in International Agriculture (CAMBIA), a close Canberra neighbour of the Australian National University. A complete list of informants and a separate list of invited attendees at the MSI workshop are included in the Appendices.[18]

Soon after I began this fieldwork, it became apparent that my goal of making a straightforward comparison between the fields of software and biotechnology with respect to the feasiblity of implementing open source principles was too ambitious. The reason was essentially that the people with whom I spoke meant too many different things by the term "open source". The Open Source Biology workshop was a turning point in terms of my conception of the project. On one view it was a great success: the attendees were interested and well-informed, the discussion was wide-ranging and robust, and the informal atmosphere allowed people to form important personal connections. Yet, on reflection, by the end of the last session we had not advanced much beyond agreeing on the need for a better solution to problems of access and participation in biotechnology and reiterating the broad differences between software and biotechnology referred to above. Across the board, I found that discussions of open source biotechnology tended to gloss over important distinctions, such as that between open source licensing and simple dissemination of a technology without obtaining intellectual property protection; they also often proceeded on faulty premises, for example that open source licensing would be incompatible with the use of the licensed technology in any commercial application or that open source development would mean excluding profit-seeking firms from the development process. Without a common analytical framework, it was difficult to establish what role different organisations might play in bringing about a move towards open source biotechnology or how different stakeholders might gain or lose from such a change. Moreover, in the absence of clear criteria for determining whether and, if so, how much the differences between software and biotechnology really mattered, simply alluding to those differences allowed skeptics to dismiss out of hand what I believed might turn out to be a very valuable idea.

These problems highlighted the fact that the concept of open source biotechnology was in a much earlier stage of development than I had at first supposed. As a result of this realisation, I decided to shift the emphasis of my research: instead of a conducting a detailed assessment of the feasibility of open source biotechnology, I would need to start by constructing a conceptual model that incorporated all the fundamental aspects of open source without losing its meaning when applied outside the software context. This new focus would not require me to abandon my original aim altogether, but I would no longer be focussed solely on the feasibility of an open source approach in biotechnology. Instead, I would

[18] Appendix A does not include anonymous informants, of which there were three.

have to confine myself to asking whether the concept of open source biotechnology would stand up to any degree of scrutiny – in which case its feasibility under a range of circumstances would merit further investigation – or whether it would turn out on first serious examination to be a mere catchphrase or (as one speaker at an international conference in 2003 put it) "pie in the sky" notion.[19]

Given this decision, I considered how to convey a feel for my informants' struggles to come to grips with the still-embryonic concept of open source biotechnology. It was not appropriate to report on the fieldwork as if it had been a formal piece of ethnographic research, because this would have required the imposition of a greater degree of methodological rigour from the outset. However, I did decide to incorporate a number of direct quotes from interviews into the text of the thesis in order to bring the reader into closer contact with the individuals who influenced my investigations. The decision to incorporate direct quotes raised the ethical question of how best to protect the privacy of these individuals: none had been explicitly approached as a research subject, but information about speakers' roles and identities would in many cases help to illuminate the quoted material. The policy I have adopted is to identify informants by name when they were speaking as experts on matters of fact or expressing sentiments that they have repeated on the public record, and in other cases to make a judgment as to whether any legitimate interest might be compromised by full identification. If not, the informant is named; if there was any doubt, I have either sought explicit permission to identify the informant or, where this was not practicable (permission was never actually refused), provided information about the speaker's role sufficient to put the quote in context but not to allow precise identification.

The substantive chapters of this thesis can be divided roughly in half according to subject matter: chapters 2, 3 and 4 deal with the desirability of an open source approach to biotechnology, while chapters 5, 6 and 7 deal with the question of feasibility. Chapter 2 is written as an historical review of legal, economic and sociological literature dealing with the likely impact of intellectual property rights in biotechnology-related innovations. In addition to demonstrating the importance, in theoretical terms, of access to and participation in biotechnology research by a diverse range of actors, this chapter introduces concepts that inform the discussion in later chapters, including the "data stream" analysis of scientific research and the idea that information exists in varying degrees of codification. Chapter 3 shifts the focus from theory to a question of empirical fact: has the expansion of intellectual property protection that has accompanied the growth of a global commercial biotechnology industry hindered scientific progress in this field? The chapter begins by asking whether a "tragedy of the anticommons" has eventuated in either medical or agricultural biotechnology, then broadens the discussion to take into account important structural effects of intellectual property rights on the direction of research and development in both industry sectors. Chapter 3 concludes by asserting the need for a more effective mechanism for promoting broad participation in biotechnology-related innovation, and

[19]Rai (2003).

suggests that open source software licensing might provide some valuable inspiration. Chapter 4 introduces the concept of open source software as both a licensing scheme and a development methodology. The history of open source reaches back to the conventions of information exchange adopted by the first computer scientists immediately following the second world war, as documented in Steven Levy's *Hackers*,[20] and more recently by Steven Weber in *The Success of Open Source*,[21] but chapter 4 picks up the thread with Richard Stallman's initiation of the GNU project and the invention of "copyleft" software licensing.[22] Much of the chapter is devoted to a detailed overview of the Open Source Definition, which sets out the criteria used by the open source movement's dedicated advocacy organisation and licence certification body, the Open Source Initiative, to determine whether particular software licences are "open source".

This overview of the Open Source Definition provides a starting point for chapter 5's exploration of the applicability of an open source licensing model in biotechnology. A definitive account of the issues that arise in translating open source licensing principles into the biotechnology context would be beyond the scope of this preliminary study, and in any case I am not qualified to write it. Nevertheless, I have considered it worthwhile to include some technical material (despite the fact that it is of necessity both very general and rather dry) in order to demonstrate how critical the adoption of a particular set of licensing criteria has been to the overall success of the open source model in software and to illustrate the need for careful attention to detail in the construction of a functionally equivalent set of criteria in biotechnology. Chapter 6 addresses the other key aspect of the open source approach identified in chapter 4, that of open source as a loosely defined but characteristic mode of innovation. This chapter, the longest in the thesis, carries the main burden of establishing an analytical framework for comparing open source software development with biotechnology research and development and of demonstrating that the differences between the two fields are not such as to rule out the possibility of successfully implementing open source principles in a biotechnology context. The structure of chapter 6 is drawn largely from the innovation management literature on user innovation, which also underpins the discussion in chapter 7 of the potential economic significance of open source biotechnology. Chapter 7 examines the commercial applicability of the open source model in biotechnology from the perspective of individual industry participants, then moves into conjecture, based on analyses of the impact of open source on the structure of the software industry, as to the possible future of open source research and development in biotechnology. The chapter closes with a brief account of moves within the industry towards an open source model of licensing and innovation.

[20] Levy (1984).

[21] Weber (2004).

[22] Note to readers of the corrected version: readers who are familiar with open source software licensing are advised to skip this chapter.

Chapter 2

Theoretical perspectives

2.1 Introduction

Since the 1960s, legal theory has expanded to take into account insights drawn from other disciplines, especially economics and sociology. Economic approaches to law have greatly enriched the theoretical framework of legal thought, while sociological approaches have emphasised the importance of empirical data as a basis for sound legal policy. Because the strengths and weaknesses of these two styles of legal thinking tend to complement each other, combining economic and sociological perspectives on particular legal issues can greatly enhance understanding of those issues.[1]

Both economics and sociology have traditionally had something to say about intellectual property rights. This chapter reviews traditional and more recent thinking in both disciplines about the likely impact of strengthening intellectual property in biotechnological innovations, especially those that have value not just as end products but as tools for further innovation.

This review of the literature reveals that even though early economists and sociologists of science came to opposite conclusions about the best way to promote innovation in the context of scientific research, the two disciplines have now largely converged on a view of the process of innovation that emphasises the need for interaction among many independent participants, as far as possible unfettered by restrictions on the transfer of relevant information and materials.

2.2 Commercialisation of biotechnology research and development

The first genetically engineered organisms were created in the United States in 1973 by academic scientists Herbert Boyer and Stanley Cohen.[2] Five years later, Genentech – the company founded by Boyer and venture capitalist Robert Swanson to commercialise the new technology – announced the synthesis of human

[1] See Galanter & Edwards (1997); Dau-Schmidt (1997).

[2] Cohen et al. (November 1973); Morrow et al. (May 1974); Chang & Cohen (April 1974).

insulin in bacterial cells.[3] This remarkable early success captured the imagination of investors, and when Genentech went public in 1980, its stock underwent the most dramatic escalation in value in Wall Street history.[4] By the end of 1981, over 80 new biotechnology firms had been established in the US.[5] Two decades on, biotechnology forms the basis of a multibillion-dollar global industry.[6]

Historians of the biotechnology industry have observed that despite industry legend surrounding the explosive growth of the 1970s and 1980s, neither the technology itself nor the commercial exploitation of academic life sciences research were without antecedents.[7] What was new was the convergence of a number of factors that brought molecular biology research and product development closer together than ever before. These included declining public support for scientific research; ready availability of venture capital and other private funding sources; changing expectations about the roles of academic institutions; the technical achievements of Cohen, Boyer and many others;[8] and, in 1980, two significant legal changes – one legislative, the other the result of a landmark court decision – that were to accelerate the rate of commercialisation through the rest of the decade and beyond.[9] Earlier links between university scientists and industry had largely preserved the boundaries between the academic and commercial spheres.[10] From the late 1970s, those boundaries became increasingly blurred.[11]

Following World War II, academic science had enjoyed relative independence from external influences as the result of large grants from national governments, distributed by scientists themselves through funding agencies such as the United States' National Research Council.[12] The emergence during the 1970s and early 1980s of closer relationships between universities and industry – particularly those in which individual scientists or their institutions expected to profit directly from the commercialisation of research[13] – generated lively discussion among academic scientists about the possible impact of commercialisation on the integrity of the research process.[14]Specific concerns expressed by scientists and observers from the beginning of the 1980s related to the prospect of corporate in-

[3]Genentech website, http://www.gene.com/gene/about_genentech/history/#1976, last accessed 18 March 2004.

[4]"Biotech At 25: The Founders", University of California at Berkeley Library website http://bancroft.berkeley.edu/Exhibits/Biotech/25.html, last visited 4 March 2002.

[5]INTECH (1991), p.5.

[6]For an overview of the modern biotechnology industry, see generally Ernst&Young (2000).

[7]Bud (1998); Kay (1998); Creager (1998).

[8]Thackray (1998), Introduction, p.ix; Etzkowitz (1989), pp.15-16; Owen-Smith & Powell (2001), p.2.

[9]Bayh-Dole Act (Act of Dec. 12, 1980, Pub. L. No. 96-517, 6(a), 94 Stat. 3015, 3019-28 (1980), codified as amended at 35 U.S.C. 200-212 (1994)); *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980).

[10]Etzkowitz (1989), p.15.

[11]Blumenthal et al. (1986); Blumenthal (1992); Blumenthal et al. (1996a); Blumenthal et al. (1996b); Blumenthal et al. (1997); Campbell et al. (2000).

[12]Etzkowitz (1989), p.15.

[13]Kevles (1998), pp.66-67.

[14]For example, see Fox (1981). In 1981, Congress held a series of hearings on the impact of commercialisation of academic biomedical research; see Eisenberg (1987), p.178, note 3.

terests dictating the direction of research, possible deterioration in the quality of research due to the undermining of traditional peer review mechanisms, exploitation of graduate students and postdoctoral researchers, divided loyalties and financial conflicts of interest, and the danger that academic scientists would lose their credibility as impartial experts on matters of science policy.[15] But the overarching concern was that, by disrupting relationships among scientists and interfering with the flow of scientific communication, commercialisation would hinder the overall progress of science.[16]

2.3 Scientific progress and the "norms of science"

To understand the source of this anxiety, it is necessary to have some familiarity with contemporary conceptions of the nature of science and the scientific enterprise.

The concept of "scientific progress" dates from the sixteenth and seventeenth centuries, and since that time has been linked with an ideal of free and open dissemination of scientific information.[17] During the 1940s, sociologists of science formalised this conceptual link by theorising that a norm of common ownership of research results – the norm of "communism" or "communalism" – functioned together with other scientific cultural norms to align the interests of individual scientists with the overarching institutional goal of scientific progress, defined as the extension of knowledge certified as true.[18] According to sociologist Robert K. Merton and others of his school, these norms were not codified or necessarily explicit; rather, they operated as "prescriptions, proscriptions, preferences and permissions... legitimated in terms of institutional values... transmitted by precept and example and reinforced by sanctions".[19] Their existence could, it was argued, be inferred from a moral consensus among scientists expressed "in use and wont, in countless writings on the scientific spirit and in moral indignation directed toward contravention of the ethos". [20] Disagreement among scientists was acknowledged by sociologists, but regarded as deviant and generally attributed to insufficiently internalised norms.[21]

The "norms of science", especially the norm of communism, reflected what sociologists regarded as the essentially cooperative and cumulative nature of scientific research. In order to collaborate and build on each other's work, scientists

[15]Fox (1981); Eisenberg (1987), p.178, note 3.

[16]For example, see Fox (1981), p.41.

[17]Eamon (1975), p.335 and pp.338-340.

[18]"Certified knowledge":Merton (1957), pp.40-41:552-553. During the same period, philosophers of science – logical empiricists led by Karl Popper – developed and elaborated their own picture of how science behaved. Despite differences of emphasis, both disciplines at this time were preoccupied with explaining what seemed a surprisingly high degree of agreement in science: Laudan (1982).

[19]Merton (1957), p.39:551; see also Nowotny & Taschwer (1996).

[20]Merton (1957), p.40:552

[21]Laudan (1982), p.260.

needed access to a common fund of knowledge. The norm of communism was supposed to encourage scientists to contribute to this common fund by communicating the results of their research to other scientists: the norm ensured that secrecy was condemned, while timely, open publication was rewarded. [22]

The norm of communism was also supposed to preserve scientific knowledge within the public domain, where it could be freely used and extended. Like the ideal of open dissemination of scientific knowledge, the notion that science should be publicly owned and pursued in the public interest has long been associated with the concept of scientific progress.[23] In the 1930s and 1940s, leaders of the "radical science movement", from which the research agenda adopted by early sociologists of science evolved, set out to consider how science could best be organised for maximum social benefit.[24] Thus, Merton intended his examination of the normative structure of science as an introduction to a larger problem: the comparative study of the structure of science under different political conditions.[25] He argued that because the institution of science is only a part of the larger social structure, with which it is not always integrated, the scientific ethos can be subjected to serious strain when the larger culture opposes a scientific norm.[26] In the case of the norm of communism, Merton saw such conflict arising out of the incompatibility of the scientific norm with the definition of technology as private property in a capitalist economy. He wrote: "The substantive findings of science... constitute a common heritage in which the equity of the individual producer is severely limited. An eponymous law or theory does not enter into the exclusive possession of the discoverer and his heirs, nor do the mores bestow upon them special rights of use and disposition. Property rights in science are whittled down to a bare minimum by the rationale of the scientific ethic. The scientist's claim to 'his' intellectual 'property' is limited to that of recognition and esteem."[27] Merton referred specifically to patents, with their exclusive rights of use (and, he remarked, often non-use), and to the suppression or withholding of knowledge (for example, through trade secrecy) as opposing the rationale of scientific production and diffusion.[28]

Returning to the trends of the 1970s and 1980s: it was clear that if early sociologists of science were correct in their analysis of the normative structure of scientific research, the rapid commercialisation of biotechnology research constituted a threat to scientific progress because it might tip the balance of incentives away from contribution to a common fund of knowledge and towards restrictive communication practices motivated by the prospect of private ownership of scientific

[22]Merton (1957), p.45:557.

[23]Eamon (1975), pp.338-340.

[24]Nowotny & Taschwer (1996), p.xvii.

[25]Merton (1957), p.40:552.

[26]Merton (1957), p.41:553. In each case of conflict between a norm and the wider social values, Merton's starting assumption was that the guiding principles of democracy (though these may be inadequately put into practice) are aligned with the scientific norm, so that scientists find themselves subject to less conflict the more democratic the society: p.40:552.

[27]Merton (1957), p. 44:556.

[28]Merton (1957), p.46:558.

knowledge. The pressure experienced by academic scientists to commercialise their research appeared to be an example of the larger culture distorting a more or less efficient existing professional ethic, in particular the norm of communism, and thereby impeding scientific progress.

In fact, by the time Cohen and Boyer made their historic discovery, many sociologists of science had begun to doubt the reality of normatively controlled behaviour, preferring instead to treat references to norms in the course of scientific debate as rhetorical tools or rationalisations for interest-driven behaviour.[29] Nevertheless, the idea of scientific norms remained influential both within and outside the discipline of sociology.

2.4 Insights from the new sociology of science

The reason why mainstream sociologists of science largely abandoned models of scientific research based on Merton's theory of scientific norms relates to the historical development of the discipline. Early philosophers and sociologists of science regarded science as unique among intellectual activities. In particular, they thought that science as a discipline was defined by a high level of agreement among scientists about assertions of fact. For this reason early sociologists of science, including Merton, were chiefly concerned with constructing models to explain the phenomenon of scientific consensus.[30] However, during the 1960s and 1970s – influenced by developments in the history and philosophy of science – sociologists of science began to take a more cynical view of competition and collaboration within scientific communities. Questioning the existence of any distinctive scientific ethos, they turned away from an idealised picture of consensus among scientists and instead became preoccupied with studying scientific debate and disagreement.[31] As a result of this shift in focus, many of what had been central issues in the classical sociology of science came to be generally neglected, among them issues relating to intellectual property and the openness of scientific communication. Moreover, because the new "sociology of scientific knowledge"

[29]See Mulkay (1976). Laudan has identified a number of criticisms of Merton's theory in more recent sociology of science literature (Laudan (1982), p.261.). First, disagreements among scientists cannot really be treated as minor deviations from a consensual norm: as Harry Collins, Trevor Pinch and others have shown, controversy is ubiquitous in science (Laudan (1982), p.266; see also Collins & Pinch (1994)). Second, scientists who are doing their best to follow norms of disinterestedness, objectivity and rationality find themselves led to very different conclusions about what constitutes conformity with these norms: Mulkay has pointed out that since no rule can specify completely what is to count as following or not following that rule, we cannot assume that any norm can have a single meaning independent of the context in which it is applied (Mulkay (1980)). Third, violations of Merton's norms are frequent, often rewarded, and sometimes even important for scientific progress: for example, Mitroff has presented substantial evidence of successful "counternormal" behaviour (Laudan (1982), p.263; Mitroff (1974), cited in Eisenberg (1989), p.1048, note 130).

[30]Laudan (1982), pp.254-257.

[31]Nowotny & Taschwer (1996), pp.xix-xx: the biggest single influence from the philosophy of science was Kuhn (1970). See also generally Laudan (1982).

incorporates a diverse range of theoretical approaches, its insights have not been as easily accessible to scholars outside sociology as those of Merton and his colleagues.

In 1994, sociologists Stephen Hilgartner and Sherry Brandt-Rauf moved to address this problem by presenting a model of scientific exchange – the "data stream" model – incorporating insights from the new sociology of science.[32]

The first such insight is that the concept of "data" should be subjected to social analysis rather than treated in commonsense terms.[33] In contrast to earlier models of scientific research, the data stream model conceptualises data not as well-defined, stable entities – the end products of research – but as elements of an evolving data stream.[34]

Data streams have four key characteristics. First, they are composed of heterogeneous networks of information and resources, including many categories commonly used by scientists to describe the input and output of their work: data, findings, results, samples, materials, reagents, laboratory techniques, protocols, know-how, experience, algorithms, software and instruments. However, because the meaning of each of these terms is context-dependent, and each element is linked to many others in the data stream, it may be difficult to assign any given element to a single category.[35]

Second, their elements range from mundane items which are part of the ordinary social infrastructure, such as water, electricity and computers, through elements specific to a research area but widely available either free or as commercial products, such as journal articles or assay kits, to specialised elements which are not publicly available but may be disseminated through personal contacts, and finally to novel or scarce elements available only by special arrangements. Hilgartner and Brandt-Rauf remark that critical issues in the analysis of scientific access practices most often concern elements of the data stream lying towards the "novel or scarce" end of this spectrum.[36]

The third property of data streams is that different elements have different information status. At one extreme, elements of a data stream may be generally accepted as reliable and valuable, while at the other, they may be so uncertain that even the scientists who produce them doubt their credibility or usefulness. Data are constantly interpreted and reinterpreted through the research process, so that scientists' perceptions of the reliability and value of particular parts of the data stream vary with time; this can be important in decisions about access, as scientists ask themselves whether data are "ready" for dissemination, or how much data are "worth".[37]

[32]Hilgartner (1997); Hilgartner & Brandt-Rauf (1994).
[33]Hilgartner & Brandt-Rauf (1994), p.358.
[34]Ibid., p.359.
[35]Ibid., pp.359-360.
[36]Ibid., p.360.
[37]Ibid., pp.360-361. Jordan and Lynch (Jordan & Lynch (1998)) describe how the polymerase chain reaction (PCR) technique has been adapted to different circumstances in science, medicine, industry and criminal forensics. Their paper explores in detail the evolution of the information status of a molecular biological technique from unreliable to standardised.

Finally, data streams are composed of chains of products. Scientists initially record data using primary inscription devices, such as x-ray film or electrophoresis gel, then convert the data into second, third or fourth order inscriptions; materials may be processed and purified; electronic information may be subjected to a series of manipulations; and so on. Hilgartner and Brandt-Rauf argue that these translations and conversions affect access practices because they alter not only the information content and material form of the data, but also the purposes for which they can be used.[38]

The second insight that Hilgartner and Brandt-Rauf draw from recent social studies of science is that transactions involving data are negotiated within complex research networks.[39] They argue that analyses of data access patterns are often framed in terms of relationships between two parties – the primary researcher or producer of the data and the secondary researcher who wants to obtain access – but that in reality, each member of a research network is linked to many other people and organisations. Moreover, access practices are intimately involved in the construction and maintenance of such networks. Therefore, the analysis of data access practices should take account of a range of relevant actors. A decision about whether to grant access to data may involve many parties: a research team of scientists, possibly from several institutions or several fields of study, with different levels of training and of involvement in the project; government and corporate sponsors providing funds; perhaps also a host university, with all its internal bureaucracy. These parties may have different goals and differing claims to portions of the data stream, and they may disagree about the optimal means and timing of dissemination.[40] Similarly, audiences or markets for data do not necessarily consist of individuals or undifferentiated groups: they may include competing research groups, potential collaborators, authors of studies with conflicting results, gatekeepers who control key resources (e.g. department heads, corporate sponsors), potential markets for research based products, or venture capitalists.[41]

The third relevant insight from the new sociology of science is that there is a wide range of mechanisms available for granting, limiting or denying access to data, and that analysis of data access practices should take into account the incentives and strategic considerations associated with each.[42] While traditional models of data access emphasise peer recognition as a scientist's primary reward for discovery, with open publication as the primary legitimate means of achieving recognition, open publication is only one of many mechanisms for disseminating portions of a data stream. Data may be bartered in negotiations with prospective collaborators or sponsors, distributed to selected colleagues, patented, transferred by visitors being trained in new techniques, provided to a limited group on a confidential basis, bought and sold, pre-released to existing sponsors, kept

[38]Ibid., p.361.
[39]Ibid., p.358; pp.362-363.
[40]Ibid., p.363.
[41]Ibid.
[42]Ibid., p.358; pp.363-366

in the lab pending future decisions about disposition, and so on. (In other words, researchers engage in both bargaining and gift behaviours.[43]) Hilgartner and Brandt-Rauf again identify a spectrum, from limited access to widespread distribution, and argue that as access becomes more widespread, the competitive edge conferred by possession of unique data declines. Scientists can exploit this competitive edge by restricting access, using data to produce more data, or by providing carefully targeted access; or they may choose to provide widespread access in order to enhance their scientific reputation.[44] Other factors affecting decisions about how to provide access include timing, the portion of the data stream to be made available, and the costs and logistics associated with different modes of access. Hilgartner and Brandt-Rauf observe that in order to comprehend these strategic issues in relation to a particular area of research, it is necessary to acquire a detailed understanding of the structure of data streams in that area.

The fourth and final insight from the new sociology of science is the importance of examining how access practices interact with strategies for commercialisation.[45] In his 1994 article with Brandt-Rauf and more recently, Hilgartner acknowledges that legal mechanisms of commercialisation may have a significant impact on scientific data access practices, noting that the law is clearly relevant to these practices because it addresses questions of ownership and control.[46] He describes the legal approach to data ownership as atomistic: it involves plucking items from the data stream and attempting to place them into discrete categories in order to designate an end product that may qualify for some type of protection – patent, copyright, trade secrets, misappropriation, contract, or conversion,[47] while data which are not construed as falling into one of these categories are considered to fall within the public domain.[48] Distinguishing between areas in which the law offers a relatively stable set of data protection mechanisms, and areas – like biotechnology – in which the law is still evolving (so that legal and scientific practices are simultaneously constructed in part through their interaction), Hilgartner proposes that future empirical research should focus on the relationship between scientific practices and the law.[49] In particular, he believes it is important to understand how researchers try to employ legal mechanisms for controlling data access, what dilemmas and strategies are created by the disparity between the law's reductionist approach to ownership and the continuity of data streams and research networks, and how access practices, the law and the political economy of research interact to redefine legal regimes governing fast-moving areas such as biotechnology.[50]

The present study contributes to this research agenda, but for Hilgartner the

[43]Ibid., p.363.
[44]Ibid., pp.364-365.
[45]Ibid., p.358.
[46]Ibid, p.358 and pp.366-368; Hilgartner (1997), pp.7-8; Hilgartner (1998), p.202.
[47]Transferred material is bailed property.
[48]Hilgartner & Brandt-Rauf (1994), pp.366-367. Increasing use of the more general term "intellectual property" may reflect a creeping reversal of this default position.
[49]Ibid., p.367.
[50]Ibid., pp.367-368.

prior question is whether an emphasis on intellectual property in academic science should be expected to cause a reduction in scientific openness. Applying the data stream perspective, Hilgartner suggests we need answers to a series of empirical questions. Do intellectual property considerations influence what portions of data streams are provided, to whom, and when? Do they introduce new sources of delay, or change the kinds of restrictions that are placed on the use of data? Do intellectual property considerations increase the complexity and formality of negotiations over access to data, make collaborations more unstable or difficult to form, or complicate the development and maintenance of shared understandings about control over data streams that are collectively produced?[51] We examine these issues in the context of biotechnology research and development in chapter 3.

Hilgartner argues that, at any rate, we should not expect intellectual property protection to lead to an increase in openness among academic scientists: restrictions on openness motivated by possible commercial exploitation probably tend to propagate upstream from the point of potential commercialisation back into the research process, so that portions of data streams that are believed to be precursors of potentially patentable products are likely to be relatively tightly controlled.[52] He notes that existing empirical evidence suggests intellectual property considerations do actually reduce openness,[53] but warns that the effects of intellectual property protection on academic science will not be uniform across all fields, hypothesising that access practices are most intensively shaped not at the level of the discipline or field but at levels of research that can be defined in terms of a characteristic data stream and a particular competitive structure.[54]

Ultimately, in Hilgartner's view, the most important questions about scientific data access practices are normative. He asks whether the public domain should be defended against encroachment by proprietary categories of information – though in the light of sociological literature problematising the concepts of "public" and "private" in scientific research, we should perhaps prefer his alternate formulation, in which the problem is expressed as one of deciding which data access policies are most likely to contribute to research productivity while promoting other social goals.[55] We return to this question in chapter 4.

---

[51] Hilgartner (1997), p.7.

[52] Ibid.

[53] Ibid., referring to the work of Cambrosio, Mackenzie and Keating on the interaction of scientific and legal innovations in the commercialisation of monoclonal antibodies (Mackenzie et al. (1990); see also Cambrosio & Keating (1998)), to his own empirical work (see Hilgartner (1998), Hilgartner (1995)), and to the controversy which led to the formation of the Committee on Intellectual Property and Research Tools in Molecular Biology and to attempts to develop a Uniform Biological Materials Transfer Agreement (for more detail, see Enserink (1999) and Council on Governmental Relations (1996)). Hilgartner also refers to Blumenthal (1992), one of a series of survey studies investigating the effects of academic-industry relationships in the life sciences (see note 11, above.).

[54] Hilgartner (1997), p.8.

[55] Hilgartner & Brandt-Rauf (1994), p.369; see also Cambrosio & Keating (1998), p.176. Cambrosio and Keating give examples in which the private ownership of monoclonal antibodies became the key to public circulation. They argue that the issue of access pertains less to ownership in

2.5 Intellectual property law and policy developments

The reason for Hilgartner's focus on legal mechanisms of commercialisation is that the commercialisation of biotechnology research and development in the final quarter of the twentieth century was closely linked with the evolution of US intellectual property law and policy.

The trend towards stronger intellectual property rights in biological innovations began with the decision of the US Supreme Court in *Diamond* v. *Chakrabarty*.[56] Before 1980, the policy of the US Patent Office was to refuse applications for patents on living organisms.[57] The basis for refusal was the long-standing "products of nature" doctrine, which specified that although processes devised to extract products found in nature could be patented, the products themselves were not patentable subject matter because they were not inventions.[58] Accordingly, when Ananda Chakrabarty applied in 1972 for a patent on a living bacterium capable of consuming oil slicks, the application was refused. Chakrabarty appealed, and in 1979 the case reached the US Supreme Court. In June 1980, by a close majority, the Supreme Court held that Chakrabarty had a right to a patent on the microorganism under the existing patent law. The majority noted that the relevant distinction was not between living and inanimate things, but between products of nature and human-made inventions; patentable subject matter included "anything under the sun that is made by man", including living organisms produced using genetic technology.[59]

Through the 1980s, further decisions consolidated the policy reversal initiated by the Supreme Court in *Diamond* v. *Chakrabarty*. In 1985, the US Patent and Trademark Appeals Board awarded a patent for a type of genetically engineered corn, holding that the general availability of plant patents had not been restricted by the passage of legislation granting specific plant patent and plant variety rights protection.[60] In 1987, it confirmed that, in principle, patents could be granted on nonhuman higher animals.[61] By 1988, the Patent Office's willingness to grant a patent to Harvard University on "any nonhuman mammal transgenically engineered to incorporate into its genome an oncogene tied to a specific promoter" – exemplified by the famous (or infamous) oncomouse – indicated that the turnaround was complete.[62]

A second significant development in US intellectual property law and policy was the passage in 1980 of the Patent and Trademark Law Amendments Act (P.L.

itself, or to the distinction between public and private sectors of the national economy, than to the construction of an infrastructure that allows specific techniques or tools to be transferred from local to extended networks. Private companies may be part of such an infrastructure.

[56] *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980).

[57] The only exception was statutory: the Plant Patent Act 1930 allowed patenting of plants that could be reproduced asexually. See Kevles (1998), p.66.

[58] Kevles (1998), pp.65-66, citing Ex parte Latimer, 1889 Dec. Com. Pat. 123.

[59] *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980) quoting SEN. REP. NO. 1979 (1952).

[60] *Ex parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. & Interferences 1985).

[61] *Ex parte Allen*, 2 U.S.P.Q. 2d 1425 (Bd. Pat. App. & Interferences 1987).

[62] Leder et al., *Transgenic Nonhuman Animals*, United States Patent No. 4,736,866,12 April 1988.

96-517), more commonly known as the Bayh-Dole Act.[63]

In the US, the enormous increase in federal funding support for scientific research following World War II had been explicitly intended as a vehicle for enhancing the economy through transfer of scientific discoveries from the laboratory via industry to the marketplace.[64] By the late 1970s, policymakers recognised that despite the development of a substantial knowledge base established with federal funds at leading public and private research universities, most of this knowledge had not been successfully translated into economic development.[65] In the face of competitive pressure on US industry, and concerned about an apparent decline in American innovation, the federal administration decided that the technology transfer problem was due to its existing patent policy.[66] Up until 1980, federal funding agencies generally retained ownership of intellectual property rights arising out of funded research as a public resource; exceptions were rare and required the funding recipient to negotiate a lengthy and difficult waiver process.[67] Government policy dictated that licences be granted non-exclusively, with the result that potential private sector licensees were discouraged by the prospect of competition from investing in and developing new products.[68] In 1980, legislators and the administration concluded that the presumption of ownership of patents arising from federally funded research should be reversed. Despite ongoing controversy, the Bayh-Dole Act was enacted into law on 12 December 1980.[69] Under the Act, universities and small businesses were permitted to elect ownership of inventions made under federal funding; exclusive licensing was also permitted, provided the licensee undertook diligent commercial development of the invention, while the government retained a royalty-free, non-exclusive licence to practise the invention for government purposes.[70]

The impact of the Bayh-Dole Act was not immediate, but it was dramatic. Certainty of title to inventions, together with uniform procedures and the ability of universities to grant exclusive licences, provided a secure footing for industry investment in university research. The Act has been identified as one of the main drivers behind the development of university-industry research collaborations in the 1980s, with most active licences being in the area of life sciences, where most academic research was federally funded through the National Institutes of Health (NIH).[71]

---

[63] Above, note 9.

[64] Council on Governmental Relations (1999), p.1.

[65] Etzkowitz (1989), p.16.

[66] Council on Governmental Relations (1999), p.1.

[67] Ibid., p.2.

[68] Ibid.

[69] The Act became effective on 1 July 1981 and was amended by P.L. 98-620 on Nov 8, 1984. The finalised and consolidated provisions appear at 37 CRF Part 401 (52 FR 8552, March 18, 1987).

[70] Council on Governmental Relations (1999), p.6. Subsequent legislative initiatives broadened the reach of the Act even further by relaxing anti-trust restrictions on joint funding of research and development, and by authorising federal laboratories to enter into cooperative research and development agreements with private firms and universities. See generally Council on Governmental Relations (1999).

[71] Ibid., p.2.

2.6 Questioning the scope of protection

Both the developments outlined above were justified by reference to the supposed incentive function of patent law (the primary intellectual property regime relevant to biotechnology). In the case of the Bayh-Dole Act, the relevant incentive was the incentive to develop an existing invention, the incentive to innovate.[72] Amicus curiae briefs in the *Diamond* v. *Chakrabarty* case also referred to the incentive to innovate, but in addition, the Genentech and Pharmaceutical Manufacturers' Association briefs emphasised a different kind of incentive. They argued that allowing patents on living organisms would keep genetic engineering research "out in the open" because patents compelled publication of the means and methods that led to a patentable product. In other words, they argued that patents provided an incentive to disclose the results of research.[73]

At first glance, this argument – one of several traditional justifications for patent laws developed in the midst of recurring controversies over the past several centuries – seems to contradict the reasoning, described above, behind concerns that patents and other forms of intellectual property protection would provide a disincentive to open communication among scientists.[74] This apparent contradiction disappears on consideration of the context in which the patent incentive was expected to operate: against a background of industrial secrecy, patent protection may well promote disclosure. But what becomes of this argument if the alternative to patent protection is not secrecy, but (relatively) free and open publication? This question has particular poignancy in the United States, where Article 1, Section 8 of the Constitution empowers Congress to enact intellectual property legislation only as a means to "Promote the Progress of Science and useful Arts".

In 1987, legal academic Rebecca Eisenberg published a paper titled "Proprietary Rights and the Norms of Science in Biotechnology Research", in which she conducted a detailed examination of the interaction of proprietary rights in biotechnology with traditional (Mertonian) scientific norms.[75] Eisenberg concluded that although patent protection sat better with traditional norms than did trade secret protection, the incentives of patent law clashed with those of traditional norms in relation to the timing of knowledge dissemination and the abil-

[72]Ibid.

[73]Kevles (1998), p.67.

[74]In sixteenth- and seventeenth-century Britain, controversy surrounded the Crown's abuse of the royal prerogative and its use of patents as a source of patronage and revenue: Ricketson & Richardson (1998), pp.544-547. The anti-patent movement re-emerged during the Industrial Revolution, and again in the 1860s, when the main focus was on the restraining effects of patents on industry and free enterprise: Ricketson & Richardson (1998), pp.556-557. The movement collapsed during the Great Depression, but at the end of the twentieth century the shift towards an information-based global economy again sparked fierce debate over the value of intellectual property protection. Persistent opposition to patent laws over the years has forced proponents to develop theories justifying patent protection. Some have relied on notions of justice: see chapter 3: "Locke, labour and the intellectual commons", in Drahos (1996). Other justifications are considered below (section 2.7).

[75]Eisenberg (1987).

ity of scientists to use and extend new discoveries. With respect to knowledge dissemination, Eisenberg argued that because disclosure requirements under the patent law were in some ways stricter than under traditional norms, patent laws might actually work to reinforce existing norms, at the same time countering commercial pressures in the direction of trade secrecy by granting a property right that would survive disclosure.[76] On the other hand, she noted that many scientific discoveries may become eligible for patent protection only at a much later stage in the research process than they would normally be ripe for publication (the primary traditional means of disseminating scientific knowledge).[77] Because a patent cannot be granted for an invention which has already been disclosed, this meant that the trend towards patenting might result in substantial publication delays and the consequent slowing of related research projects which might have been helped by access to published data.

Eisenberg further pointed out that although patents might not prevent disclosure altogether, disclosure is only one side of the patent law bargain. In order to build on discoveries disclosed by one scientist, other scientists must be able to apply the discovery; but while publication of results in a journal article or at a conference makes those results freely available, in the patent system disclosure marks the beginning of a long period of exclusive possession.[78] Eisenberg speculated that the adverse impact of exclusivity on scientific research was likely to be greatest in relation to inventions which are primarily useful for research rather than commercial applications, and that this impact was likely to be exacerbated in circumstances where the patentee is reluctant to grant licenses to other researchers – out of a desire to prevent competition, because use of the invention in further research may undermine the future value of the patent by facilitating inventing around the patent, or because by preserving exclusivity in subsequent research the patentee can maximise future claims to priority of discovery both for scientific recognition and patent purposes.[79]

Of course, as Eisenberg went on to acknowledge, patent exclusivity is not absolute: certain uses of an invention during the patent term do not constitute infringement.[80] In her 1987 article, and again in a 1989 article entitled "Patents and the Progress of Science: Exclusive Rights and Experimental Use", Eisenberg examined the rationale and scope of the "experimental use" defence to patent infringement.[81] The appropriate scope of the defence, she argued, was a question of balance: too narrow a defence could stifle basic research, while too broad could cause industrial sponsors either to lose interest in biotechnology research or to rely on trade secrecy instead of patent protection.[82] Eisenberg concluded that the case for allowing a defendant to escape infringement liability on the grounds

[76]Ibid., pp.206-207.
[77]Ibid., p.207.
[78]Ibid., p.217.
[79]Ibid., pp.217-218.
[80]Ibid., p.219.
[81]Ibid., pp.220-224; Eisenberg (1989).
[82]Eisenberg (1987), p.224.

that use of the patented invention was for experimental purposes was strongest where the user was attempting to check the adequacy of the patent specification or the validity of the claims, or to devise alternatives to the patented invention, and weakest where the invention is essentially being used as a tool in an unrelated research effort – in other words, where the user is effectively an ordinary consumer of the invention.[83]

These early papers dealing with the impact of intellectual property protection on the progress of scientific research in biotechnology are significant because they anticipated key aspects of the present debate over the appropriate scope of intellectual property rights in that field. During the 1990s, as research scientists and their institutions became more familiar with patenting and other aspects of commercialisation, legal discussion shifted from the broad question of whether research discoveries should be protected by intellectual property laws at all to subtler questions about what sorts of research discoveries should be protected and how to preserve the benefits of intellectual property while minimising interference with scientific progress.[84] In her 1987 and 1989 articles, Eisenberg had drawn attention to possible problems associated with patenting of inventions which are primarily useful as tools for further research and to issues surrounding licensing of such inventions. As it turned out, during the 1990s perceived problems of access to proprietary research tools became the focus of heightened controversy within the academic biotechnology research community.[85] Thus, by the late 1990s, intellectual property policy in relation to proprietary research tools was of intense practical interest to researchers, as well as being of theoretical interest as an illustration of the difficulty of reconciling the rationale for intellectual property protection of research discoveries with the need for scientists to be able to build freely on those discoveries in the interests of scientific progress.

2.7 Economic justifications for intellectual property protection

The extension of legal protection to intellectual property has been justified by reference to both moral and economic arguments, but in countries with a British legal heritage the latter have been the most influential, especially in relation to patents. As noted above, the US Constitution incorporates an exclusively instrumental justification for patent legislation, and there is no doubt that today, intellectual property protection is regarded by policymakers at both national and international levels primarily as a means of stimulating technological innovation.[86]

[83]Eisenberg (1989), pp.1074-1078; see also Eisenberg (1987), pp.224-225.

[84]National Research Council (1997), Preface.

[85]Ibid., Introduction.

[86]Loughlan provides a modern perspective on moral justifications for intellectual property rights: "there is no widespread social and economic acceptance of a general proposition that persons ought to be legally entitled to regain the full value of their labour. What do you think capitalism is about?" Loughlan (1998), p.15.

The literature dealing with economic justifications for intellectual property protection is enormous. Fortunately, a paper by Richard Nelson and Roberto Mazzoleni provides a convenient entry point. Nelson and Mazzoleni identify four economic theories purporting to explain how patent protection promotes technological innovation. They are the "invention-inducement theory", the "disclosure theory", the "development and commercialisation theory" and the "prospect development theory".[87]

The invention-inducement, disclosure and development and commercialisation theories all treat patent protection as a response to potential market failure resulting from the "free rider" problem. A free rider is someone who imitates and thereby gets the benefit of an invention without having made any significant investment of time, effort, skill or money. Assuming that inventions are easier to copy than to make, a rational actor would not choose to invest the resources necessary to make a new invention or to develop and commercialise an existing invention – or at any rate would not choose to disclose a new invention – without some means of protecting that investment. The invention-inducement theory, the disclosure theory and the development and commercialisation theory each postulate that, by conferring on the patentee or his or her assignees the exclusive right to commercially exploit an invention for a limited time, patent rights create a needed economic incentive to engage in the relevant phase of the innovation process.

According to these theories, the social benefit of promoting innovative activity through exclusive patent rights comes at a social cost. In effect, a patent is a limited monopoly: an opportunity to create a legally enforced market structure in which the patent holder can charge more for his or her product than would be possible in a competitive market.[88] Because monopoly rights impose a cost on the community by way of increased prices and reduced output, patent laws should be designed to grant patents only for inventions which would not otherwise have been made, or which would not otherwise have been made available to the community through disclosure or development and commercialisation. This leads to a fundamental problem with incentive arguments in favour of patent rights. To justify patent protection in any given context – for example, for research tools in biotechnology – it is necessary to demonstrate first, that some extra incentive to engage in innovative activity is needed; second, if it is needed, that the patent incentive is likely to be effective; and finally, that there is no better way to achieve the desired result. But this is difficult, perhaps impossible, to do.[89] Patent own-

[87]Nelson & Mazzoleni (1997). Nelson and Mazzoleni give a brief outline of each theory as follows (p.1): "Invention-inducement theory: The anticipation of receiving patents provides motivation for useful invention. Disclosure theory: Patents facilitate wide knowledge about and use of inventions by inducing inventors to disclose their inventions when otherwise they would rely on secrecy. Development and commercialisation theory: Patents induce the investment needed to develop and commercialise inventions. Prospect development theory: patents enable the orderly exploration of broad prospects for derivative inventions."

[88]Loughlan (1998), p.93.

[89]Methods for empirical studies have included examination of historical records of industrial development for countries with and without patent systems; qualitative research to determine

ership is not the only way to obtain an economic return from new inventions: for example, innovators may enjoy a pioneer advantage even in the absence of patent protection. As sociological studies of science show, economic incentives are not the only kinds of incentives which motivate innovation.[90] And while empirical evidence suggests that overall levels of innovation do respond to economic stimuli, governments have at their disposal a range of economic instruments for stimulating innovation other than patents, including the provision of research funding or venture capital, tax concessions, procurement policy, export development grants, tariffs and bounties.[91] With respect to the disclosure theory, it has been argued that patents may not in fact create an incentive to disclose inventions that would otherwise be kept secret, because patent protection is most attractive relative to trade secrecy for those very inventions which could not easily be kept secret for long.[92] Given this complexity, it is not surprising that empirical assessments of the incentive function of patent protection have been inconclusive.

Nelson and Mazzoleni's fourth theory, the prospect development theory, differs from the older incentive theories just discussed in that it treats the patent system not merely as a device to enable the capture of returns on investment in innovation, but also as a system for efficiently allocating resources to the development of existing inventions. Introduced by Edmund W. Kitch in 1977, the prospect development theory postulates that granting broad patents on early stage inventions allows patent holders to coordinate subsequent research and development within the area of the patent claim (the "prospect"). If the patent holder has an exclusive right to exploit the new technological prospect, later arrivals will be unable to derive economic benefit from developing the prospect unless they negotiate directly with the patent holder to obtain licences to the underlying technology. Thus the patent holder becomes a link among all those working to develop the prospect, preventing wasteful duplication of effort and facilitating the transfer of information.[93]

---

the impact of patent incentives on research and development decisions in firms; and measurement of the difference between private and social rates of return to investments in research and development. Eisenberg (1989), pp.1031-1033.

[90]Also note in this connection the comments of Burger CJ, delivering the judgment of the court in Diamond v Chakrabarty (1980) 447 US 303 at 317-318: "It is argued that this Court should weigh... potential hazards in considering whether respondent's invention is patentable subject matter.... We disagree. The grant or denial of patents on microorganisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides."

[91]Eisenberg (1989), p.1031, note 59.

[92]Long-term secrecy is not always feasible in relation to a new invention, for example because marketing the invention as a product provides an opportunity for reverse engineering (see chapter 6, section 6.3). In that case, there is no need to provide an incentive to disclose the invention – it will be disclosed anyway. But where long term secrecy is feasible, the inventor may have little to gain from patent protection, which may not last as long as a well-kept trade secret, and which may be difficult to enforce if infringers are also able to keep their use of the invention secret. See Eisenberg (1989), pp.1028-1029.

[93]Kitch (1977), pp.276-279.

In Kitch's view, the prospect function of the patent system enhances its public welfare effect. However, the prospect development theory as a justification for patent rights has a twist in its tail when applied to research tools in biotechnology. As Nelson and Mazzoleni point out, the assumption that development of technological prospects is most efficient when it is centrally coordinated by the patent holder is inconsistent with the scientific ideal of individualism and independence in research, which is based on the belief that coordination or central planning of research impedes scientific progress by weakening the initiative of researchers and substituting the judgment of the co-ordinator for that of the individuals who are actually immersed in the details of the research.[94] Sociologists of science have argued that the most efficient possible organisation of scientific research involves independent initiatives by competing scientists working with knowledge of each other's achievements.[95] Even where imperfect knowledge leads to duplication of effort, such duplication may be valuable: for example, multiple overlapping research efforts may improve the impact and accessibility of new research claims or help establish their validity, while different researchers may make different mistakes, interpret results differently or perceive different implications of the same results, thereby achieving greater overall understanding.[96]

Assuming both Kitch and the sociologists of science are correct – that is, assuming that patents do function as a claim system for new technological prospects, but that innovation in relation to research tools in biotechnology proceeds most efficiently by way of independent initiatives on the part of many different researchers – it follows that granting broad patents on early stage inventions in biotechnology may actually threaten innovation by forcing subsequent researchers to enter into potentially costly license negotiations with the patent holder. The unattractive alternative would be for later arrivals to give up hope of deriving economic reward from working on the prospect, provided of course that the work did not have to be abandoned altogether for fear of infringing the patent. The higher the transaction costs associated with obtaining a license from the patent holder, the greater the likelihood that a prospect will not be efficiently developed. Thus, the implications of the prospect development theory for patent protection of research tools turn on whether the transaction costs of patent licensing are assumed to be high or low.

[94]Nelson & Mazzoleni (1997), p.6; Eisenberg (1989), p.1060.

[95]Eisenberg (1989), p.1061, citing Michael Polanyi, "The Republic of Science: Its Political and Economic Theory" (1962) 1 *Minerva* 54.

[96]Eisenberg (1989), pp.1063-1065, citing works by Robert K. Merton and Warren O. Hagstrom. According to Kitch, the patent system cannot perform a prospect function in the context of basic scientific research because it is impossible to fashion a meaningful property right around a mere discovery or explanation of scientific phenomena. However, he does believe that basic research faces the same problems of coordination among researchers as are found in applied research, and suggests that the prospect function performed by the patent system in relation to applied research may be performed in relation to basic research by peer review procedures for research grant applications: Kitch (1977), pp.288-289.

2.8 An information economics perspective

Kitch's acknowledgement of the information function of patents reflects an important shift in economic thinking about patents since the 1960s. Until that time, economic discussion had centred around the role of patents in facilitating product markets by allowing owners of goods to sell the goods separately from the associated intellectual property.[97] However, in 1962 Kenneth Arrow observed that patents and other intellectual property rights also facilitate markets in information.[98] In the commercial world, the integration of valuable information from a range of sources requires firms to bargain for the transfer of that information. But in the absence of patents, such bargaining runs into difficulties. If the owner of information discloses it to a prospective buyer, the buyer has obtained the information for free. On the other hand, if the owner does not disclose the information, the buyer will be unable to judge its value and will therefore be unwilling to pay the asked price. A patent allows the owner of the information to disclose it to prospective buyers without losing its value; at the same time, the parties may reach an agreement about the transfer of related information not directly covered by the patent, for example information about how to apply the technology efficiently ("know-how"). Although Kitch did not refer directly to Arrow's paper, his article describes the information aspects of patents in essentially these terms.[99] Arrow's observation switched the focus of economic discussion from product to information markets and eventually triggered further insights into the relationship between information flow and the patent system, including insights about the significance of transaction costs.

In his 1996 book *Understanding Novelty: Information, Technological Change, and the Patent System*, Thomas Mandeville builds on Arrow's work on information markets to develop a new economic theory of the patent system.[100]. Mandeville observes that although conventional economic theories of the patent system do not give clear policy guidance as to the appropriate scope of patent protection, they do seem to suggest that a strong patent system is desirable for the reasons touched on above: strong property rights enable firms to control their technology and appropriate returns from it, thus providing incentives for the allocation of resources to innovative activity.[101] He proposes an alternative, "information" perspective on innovation which points to a more complex but basically contrary view of appropriate patent scope.

According to Mandeville, conventional economic theories of the patent system share two underlying assumptions. The first is that technological information is easy to copy, resulting in a lack of incentive to invest in innovation. The

[97]For a comprehensive overview of the patent system before the 1960s, see generally Fritz Machlup, *An Economic Review of the Patent System*, Study No. 15 of the Subcomm. on Patents, Trademarks and Copyrights of the Senate Comm. on the Judiciary, 85th Cong., 2d Sess. (1958).

[98]Arrow (1962).

[99]Kitch (1977), pp.277-278.

[100]Mandeville (1996)

[101]Ibid., p.9.

second is that the market is, or should be, the primary mechanism for the exchange of technological information among firms. Together these assumptions give rise to the perception that patents are necessary in order to overcome "market failure due to inappropriability" (of investments in technological innovation). But, says Mandeville, an information perspective on innovation suggests neither assumption is correct for more than a very small proportion of technological information.

To construct his information perspective, Mandeville begins by outlining the characteristics that distinguish information from material goods with respect to production and dissemination within the economy. For example, information is inexhaustible; it is accumulative, in that it grows with use and its social value is enhanced through dissemination; it has some of the characteristics of capital, in that the acquisition of information usually represents an irreversible investment; information is indivisible; the cost of producing it is independent of the scale on which it is used; and most importantly for Mandeville's arguments, the greater part of the cost of transferring information is the cost incurred by the recipient in absorbing the information and allocating scarce resources to its use.[102]

The second essential element of Mandeville's information perspective is his continuum model of technological information.[103] Defining technology as "information applied to doing things", he observes that some of this information is codified into machines, blueprints, technical and trade journal articles, and patent specifications, but that much of it exists in less codified form. For Mandeville, codification represents formalised learning – that is, learning arranged, organised into a pattern and ultimately embodied in a tangible object. Predictability is an important element of codification: a technique is not codified unless it consistently yields the same output. Thus, highly codified or tangible information appears only after substantial prior learning has taken place. At the other extreme, uncodified information consists of undeveloped ideas and unarticulated know-how; uncodified information is "pure", intangible information. Mandeville's model is a continuum because there are degrees of codification: for example, information contained in patent specifications will generally be less codified than that embodied in a prototype machine, which in turn is less codified than the information embodied in a mass produced machine. In the process of innovation, codified information evolves out of uncodified information.

Mandeville argues that although most of the real world probably lies somewhere in between the two extremes of highly uncodified and highly codified information, the bulk of economic phenomena associated with innovation occurs toward the "uncodified" end of the continuum.[104] Further, in any given field at a particular time, the proportion of technology which remains uncodified is determined both by the degree of complexity inherent in the technology and by its newness. Generally, says Mandeville, the older or more mature the technology,

[102]Ibid., pp.57-66.

[103]This model is elaborated in chapter 4, "Developing an information-theoretic perspective on innovation", Mandeville (1996).

[104]Ibid., pp.52-54.

the more it has been codified. A new industry based on a new technology is in a fluid situation where most relevant technological information has yet to be codified.[105] Compared with other industries, the biotechnology industry certainly fits this description, and many research tools in biotechnology are likely to be relatively uncodified.

Having developed his continuum model, Mandeville points out that the degree of codification of technological information affects the ease, speed and mode of its diffusion, transfer or imitation.[106] For example, while highly codified information can be communicated without the need for personal interaction, uncodified information is best communicated in person, through practice and "learning by doing". Because transfer costs are higher the less codified the information, the conventional assumption about ease of copying holds only for the highly codified end of the information spectrum; for uncodified technology, information and user costs inhibit imitation. Similarly, high transaction costs associated with the transfer of uncodified information affect the efficiency of the market as a means of coordinating its production and distribution. Mandeville illustrates this point by reference to the case of technology licensing, observing that several well-established difficulties faced by the market in this context are exacerbated in relation to highly uncodified information.[107] He argues that because the market does not work well as a facilitator of information exchange with respect to uncodified information, various nonmarket mechanisms have arisen to fill the gap. These include information transfer via hierarchies within firms, personal communication networks and personal mobility, open publication, collaboration between technology supplying firms and between technology users and suppliers, and the use of consultants.[108]

Thus, Mandeville's argument is that conventional theories of the patent system exaggerate both the problem of inappropriability and the role of the market in the innovative process. If most technological information is not easy to copy – that is, if free riding is not after all such an attractive option – and if the costs of acquiring and transmitting most technological information are much higher via the market mechanism than via a range of other existing mechanisms, then it follows that there is no need for a strong patent system to shore up a failing technology market. However, Mandeville goes further, arguing that strengthening property rights on technological information may be not just unnecessary, but actually counter-productive to overall technological advance.

According to Mandeville, an information perspective on innovation highlights the cumulative and collective nature of the process. This is in contrast to the conventional view, which emphasises the role of the individual innovating firm.[109] Innovation is cumulative in the sense that the existing stock of technology is a crucial input in the production of new technology, and collective in that it relies

[105]Ibid., pp.50-51.
[106]Ibid., p.57.
[107]Ibid., chapter 5, "Information flow mechanisms in the technological change process".
[108]Ibid., p.75.
[109]Ibid., p.9.

on the interaction of many participants. Because innovation is cumulative, it depends on information flow between present and future innovators; because it is collective, it depends on information flow among current participants, including rivals. From this viewpoint, even unauthorised copying among competing firms is beneficial to overall technological innovation because it is part of a process of transfer and learning.[110]

Patents, however, have the effect of blocking other firms from freely adopting, imitating or improving on the patented idea without the consent of the patentee. Although patents may (as Kitch theorised) encourage the diffusion of ideas by giving patent holders an incentive to sell the patented product or licence the patented technology, this occurs via the market mechanism; Mandeville argues that while patents can aid the market exchange of highly codified, tangible technology, they tend to discourage the flow of associated uncodified information via nonmarket mechanisms (absent the patentee's consent, that is exactly what they are intended to do).[111] Further, the argument that the blocking effects of patents can be overcome through licensing and other contractual arrangements is not convincing with respect to uncodified technology – that is, most technology: even if the patent holder is willing to license the technology to all comers, license agreements between arm's-length agents in the marketplace are a much slower and more costly form of information transfer than nonmarket mechanisms – and the more uncodified the technology, the higher the transaction costs.[112] While conventional theory supposes that the restrictive effects of patents can be justified if they ultimately encourage the production of new information, such a trade-off makes no sense in the realm of uncodified information because there is no clear distinction between production and use: stifling the flow of information automatically stifles its production.[113]

In a mature industry where much of the relevant technology has already been codified, Mandeville suggests that patents may not do much harm. But in new, highly innovative industries, a greater proportion of technology remains uncodified and nonmarket mechanisms are crucial to the information exchange necessary for cumulative technological advance.[114] If Mandeville is correct, strong patent protection in the field of biotechnology may be particularly harmful, impeding the necessary flow of information and deterring the formation of clusters of firms working to develop new technologies.

The relevance to the biotechnology industry of Mandeville's arguments against strong patent protection is demonstrated by the work of Walter W. Powell. Writing from a sociological perspective, Powell has argued that in fields where knowledge is developing rapidly and the sources of knowledge are widely dispersed, the locus of innovation is found in interorganisational networks. In a recent arti-

[110]Ibid., p.93.
[111]Ibid., p. 98.
[112]Ibid., p.99.
[113]Ibid., p.96.
[114]Ibid., pp.50-51.

cle,[115] he emphasises the importance of relational contracting among participants in the biotechnology industry: because the underlying science and technology is so diverse, not even the largest players can build a sufficiently strong research base to cover all areas of technical innovation, and similarly, it is not easy to assemble the full range of skills required to get new products to market beneath one roof. To compensate for this lack of internal capability, participants in the field have turned to joint ventures, research partnerships, strategic alliances, minority equity investments and licensing arrangements. Powell regards information flow as being so important in the field of biotechnology that he describes the biotechnology industry as not so much an industry in the traditional sense, as a "conduit" for a wide range of surrounding sectors to access fundamental new technologies.

Two points may be made in relation to Mandeville's theory. First, as Mandeville acknowledges, the incompatibility of property rights with pure, intangible information has always been recognised in patent law: patent doctrine excludes theories and abstract ideas from protection.[116] However, recent developments in patent law – emanating in particular from the US Federal Circuit – have expanded the boundaries of patentability to such an extent that the patent system now comes close to allowing capture of the value of information itself.[117] In a recent article dealing with the patentability of DNA sequences of unknown function, Rebecca Eisenberg warns against applying "bricks and mortar" rules to information goods;[118] Mandeville's position, that property rights are inconsistent with the economic characteristics of uncodified information, supports Eisenberg's conclusion that there are sound policy reasons to be wary of expanding property rights in intangible information.[119]

The second point is that Mandeville's vision of clusters of competing firms working on related problems within the same field, exchanging information relatively freely through a range of mechanisms and placing little emphasis on formal property rights and marketplace transactions, is strongly reminiscent of the conditions described by sociologists of science as optimal for the progress of scientific research. Mandeville is aware of this: he observes that informal personal communication, networking and incentives for individuals to communicate and signal the possession of new information seem as important in the realm of uncodified technology as they are conventionally acknowledged to be in the realm of science.[120] Thus it appears that recent sociological and economic theories about the effects of property rights on information flow and the overall pace of technological advance overlap substantially, at least with respect to leading-edge technology exemplified by many biotechnology research tools. The parallels between Mandeville's and Hilgartner's models of technological innovation are especially

[115]Powell (2001).
[116]Mandeville (1996), p.103.
[117]Eisenberg (2000), pp.791-792.
[118]Eisenberg (2000), p.796.
[119]Mandeville (1996), p.103.
[120]Mandeville (1996), p.105.

striking: for example, both postulate that the ease and mode of information transfer depends on where the particular information lies along different kinds of continuum (uncodified to codified, novel or scarce to widely available, untested to reliable); and both treat the process of innovation as a continuous cycle driven by complex interactions among many participants, present and future.

2.9 Economic studies of cumulative innovation

Other economic theorists building on Arrow's insights about the relationship between property rights and information transaction costs have also focused on the cumulative nature of innovation. Robert Merges notes the emergence in the early 1990s of a strand of economics literature attempting to describe how intellectual property rights affect bargaining between pioneer inventors and follow-on improvers in contexts where research activity is directed toward the development of improvements or applications of a previous invention.[121] This "cumulative" or "sequential" innovation literature is part of a broader economics literature on optimal design of intellectual property rights sparked by William D. Nordhaus' 1969 observation that patent length represents a trade-off between encouraging innovation and avoiding the deadweight loss associated with monopoly profits.[122] The optimal design literature considers how refinements in the duration, breadth and standard of intellectual property protection might impact on its effectiveness as an incentive mechanism.[123]

When economists began to think about how the cumulative nature of innovation affects optimal patent design, they immediately saw a problem of incentive. An invention that facilitates future innovations may be assumed to be of greater social value than one which is only useful in itself. However, in such a case it is difficult to turn social value into private value, because the incremental value of future innovations is not automatically reflected in the price of the initial invention. Unless social value can be converted into private value, so the argument goes, early innovators will have inadequate incentive to invest.[124] This problem is especially likely to arise in the case of research tools, because a large proportion of their social value resides in the innovations they facilitate.[125] A solution is to give early innovators some claim on profits arising from subsequent innovations, but this creates a new problem by reducing incentives for follow-on innovators.[126]

From this starting point, much of the literature on cumulative innovation has focused on how intellectual property rules determine the division of profits among sequential innovators, with the aim of finding those "settings" under

[121]Merges (2001), p.125; Merges (2000). Early papers include Merges & Nelson (1990) and Scotchmer (1991).

[122]Norhaus (1969).

[123]For a review of the optimal design literature, see Gallini & Scotchmer (2002).

[124]Scotchmer (1999).

[125]Gallini & Scotchmer (2002), under heading "Optimal Design: The Case of Cumulative Innovation".

[126]See Barton (1997b), text accompanying notes 12 to 25.

which profits are divided so as to respect the costs of early and later innovators and thus provide adequate incentives at every stage of the innovation process.[127] Unfortunately (though perhaps not surprisingly), increased attention to the problem of patent design in the context of cumulative innovation has not resulted in any clear guidance as to whether or how intellectual property rules should be altered in order to encourage innovation. In an article reviewing ten years' worth of literature on cumulative innovation, Nancy Gallini and Suzanne Scotchmer cautiously extract a case for broad and short patents, arguing that broad patents can serve the public interest by preventing duplication of research and development costs, facilitating the development of second generation products and protecting early innovators who lay the foundations for later development; these arguments are consistent with Kitch's prospect development model of patent function.[128] On the other hand, John H. Barton has said that the current balance of incentives is probably too much in favour of initial innovators and concludes that the best response to the recognition that innovation is cumulative is not to find ways to strengthen the control of the initial innovator, but rather to find ways to strengthen incentives and opportunities for follow-on innovators.[129]

One lesson that does emerge clearly from the cumulative innovation literature is that private contracting among rights holders can dramatically affect the optimal design of patents. The benefits of broad patents identified by Gallini and Scotchmer depend on the ability of right holders to contract around conflicts in rights: with contracting, patent holders can profit from improvements instead of being threatened by them, and will therefore ensure that they arise even if they infringe the patent; but without contracting, there is a danger that broad patents will inhibit future innovators from making improvements. In other words, whether property rights are helpful or counterproductive in encouraging innovation depends on the ease with which innovators can enter into agreements for rearranging and exercising those rights.[130]

2.10 Conclusion: the importance of scientific exchange

The commercialisation of biotechnology research and development from the mid-1970s to the present has triggered widespread concern that privatisation of scientific knowledge under an increasingly strong intellectual property protection regime could hinder the progress of science by taking the tools needed for further innovation out of scientists' hands. This chapter brought together sociological and economic perspectives on the question of what is the appropriate scope of intellectual property protection for biotechnology research tools.

[127]Gallini & Scotchmer (2002). In this connection, Barton observes that early basic research is more likely than follow-on research to have been publicly funded through research grants or other schemes which may provide adequate incentives even in the absence of intellectual property protection: Barton (1997b), text accompanying note 19.

[128]Gallini & Scotchmer (2002).

[129]Barton (2000), p.1934; Barton (1997b), text accompanying note 25.

[130]Gallini & Scotchmer (2002).

Traditional economic theories tended to support strong intellectual property rights in general, while traditional sociology of science theories emphasised the importance of free and open scientific exchange. More recent theorising in both disciplines is more nuanced, but tends to emphasise the importance of information flow for ongoing innovation. For example, Hilgartner's data stream analysis shows science as a complex decentred system of bargaining and gift relationships in which there is a variety of incentives for researchers to transfer uncodified knowledge. The explanation, applicable in both "pure" science and technology settings, is that innovation proceeds most efficiently by way of independent initiatives on the part of many different actors linked in a way that facilitates communication and provides incentives for individuals to signal the possession of new information. Intellectual property rights may or may not be useful in promoting the exchange of innovation-related information in other contexts, but could actually be harmful in biotechnology research and development, where much information is highly "uncodified" and information flow is particularly important. In particular, the dominance of the patent system as a vehicle for scientific exchange creates uncertainty because of the nature of the patent monopoly, especially problems of defining patent scope, and when scientists cannot be sure of the security of their own data streams, incentives to transfer uncodified knowledge are reduced. The probability of harm depends on the degree of the uncertainty and the severity of obstacles (transaction costs) associated with the exchange of protected scientific information and materials.

Does the current intellectual property regime in biotechnology research and development introduce transaction costs that threaten ongoing innovation? If so, what might be done to remedy this situation? We examine these questions in the next chapter.

Chapter 3

Problems and solutions

3.1 Introduction

In the previous chapter we saw that intellectual property rights might hinder the progress of innovation in biotechnology research and development. We also saw that whether this happens depends on the level of transaction costs associated with transfers of protected information and material among the various actors involved in the innovation process. In this chapter we look more closely at how transaction costs affect bargaining over proprietary research tools in the biotechnology context.

The chapter starts with a brief introduction to the concept of a "tragedy of the anticommons", a common point of departure for discussion of the effects of intellectual property rights in the biotechnology industry.[1] It goes on to examine whether anticommons tragedy has in fact eventuated in the biotechnology industry, and more generally, whether intellectual property rights in biotechnology have so far proved to be helpful in encouraging research and development directed at solving global society's most pressing problems. Empirical evidence suggests they have not, so the question arises: what should be done? The final part of this chapter gives an overview of different classes of proposed solution to problems caused by intellectual property rights in biotechnology, arguing that what is needed is a mechanism for providing affordable, accessible, unencumbered "tool kits" to allow broad participation in biotechnology research and development.

3.2 The tragedy of the anticommons

Where property rights on multiple components of a single technology are owned by a number of separate entities, the development and commercialisation of new products requires co-ordination among many different actors.[2] In a transaction

[1]The phrase "tragedy of the commons" (Hardin (1968)) was intended to suggest that not dividing the common into properties may lead to overuse and destruction. The concept of a "tragedy of the anticommons" is explained in the next section.

[2]Merges (2000). According to Graff et al., the spectrum of possible means of complementary asset co-ordination from most internalised to most externalised or "arms length" includes ac-

cost-free world, where everyone has perfect knowledge and there are no impediments or costs associated with negotiation, this would pose no problem because property rights would be transferred through private bargaining to the entity that values them the most.[3] But in reality, transaction costs are positive, and the greater the number and complexity of negotiations, the higher the transaction costs. Michael Heller has described the situation where multiple owners each have a right to exclude others from using a scarce resource as a "tragedy of the anticommons": if owners are unable to negotiate successfully for the bundling of rights so that someone has an effective privilege of use, the resource may be underused and the total potential value of the rights (private and social) may not be realised.[4]

Heller's theory of anticommons tragedy is not a new idea, but a restatement of a problem familiar to economists – that of co-ordinating complementary assets in a high technology setting. The concept of asset complementarity (possession of one asset has an effect on the marginal value of another asset) is highly relevant to biotechnology research and development because effective co-ordination can be particularly valuable during times of rapid technological change or in complex systems industries – both characteristics of the biotechnology industry – yet is made more difficult by additional uncertainty or complexity.[5] It is therefore unsurprising that it appears frequently in discussions of the likely impact of intellectual property rights in biotechnology.

The first application of Heller's theory in biotechnology was in the biomedical context. In a 1998 paper in the journal *Science*, Heller and Eisenberg pointed to the proliferation of small-scale intellectual property rights in biomedical research since the 1980s as an example of the tragedy of the anticommons: when users need access to multiple patented inputs in order to create a single useful product, granting too many property rights upstream stifles socially valuable innovations further downstream in the course of research and product development.[6] "Anticommons" terminology has since been applied to similar concerns regarding agricultural biotechnology (see section 3.4, below, p.46).

The next two sections of this chapter address the question whether anticommons tragedy has in fact eventuated in the biotechnology industry, as well as the broader question whether developments in intellectual property law and policy have adversely affected incentives to conduct socially important research and development. These sections focus on biomedical and agricultural applications of biotechnology and biotechnology research tools, to the exclusion of other areas

quisition and integration of another innovating firm; partial acquisition of such a firm; strategic research partnership with other innovating firm; ongoing research and development contract; purchase or exclusive license of patent; non-exclusive license of patent or purchase of input technology component (Graff et al. (2003b), Figure 1, p.26).

[3]Long (2000), p.827, citing R. H. Coase, "The Problem of Social Cost" (1960) 3 *Journal of Law and Economics*, and G. Calabresi and A. D. Melamed, "Property Rules, Liability Rules, and Inalienability: One View of the Cathedral", (1972) 85 *Harvard Law Review* 1089, pp.1094-95.

[4]Heller (1998).

[5]Graff et al. (2003b), pp.4-5 citing works by Teece and by Milgrom and Roberts.

[6]Heller & Eisenberg (1998).

of biotechnology research and development, for three reasons. The first is that biomedicine and agriculture are the most advanced (in terms of product development) and economically significant sectors of the biotechnology industry to date. The second is that the two fields are interesting to compare because they are closely related in terms of both the technology and the types of institutions involved, yet distinct in that they are differently funded, commercial products are aimed at different end consumers, and they are supported by different research and development communities. Finally, the legitimate end goals of biomedical and agricultural research – health and food security – are by far the most pressing concerns of the poor, who make up a large majority of the world's population. We saw in chapter 2 that the concept of "scientific progress" was originally intimately connected with an ideal of science pursued as a public good in the public interest. To the extent that privatisation of life sciences research and development undermines the global public interest, even a rapid rate of technical innovation could therefore not be described as "progress" in this sense.

3.3 Medical biotechnology

In this section we examine three questions. First, do the necessary preconditions for anticommons tragedy exist in medical biotechnology? Second, has a tragedy of the anticommons in fact eventuated in this field? Third, if there is no unambiguous evidence of anticommons tragedy in medical biotechnology, what are the biggest obstacles to achieving good health for the world's population and how do they relate to intellectual property in biomedical, including biotechnological, innovations?

3.3.1 Preconditions for anticommons tragedy

Heller stipulates two necessary preconditions for a tragedy of the anticommons: fragmented ownership of complementary assets and high transaction costs. Empirical studies have confirmed Heller and Eisenberg's assertion that the first condition is satisfied in the field of medical biotechnology: the patenting of research tools has made the patent landscape in this field more complex, and there are on average more patents (many on research tools) and more patent holders than ever before involved in a given commercialisable invention.[7] The rest of this section therefore focuses on the issue of transaction costs.

According to Greg Graff et al., the economic literature on problems of contracting for knowledge describes several general classes of problem that lead to high transaction costs.[8] The first – diffuse entitlement problems resulting from the assignment of mutually blocking property rights – corresponds to Heller's first condition for anticommons tragedy. These problems are often compounded

[7] Walsh & Cohen (2003).
[8] Graff et al. (2003b), pp.4-5.

by poorly defined boundaries among separately assigned rights. Second, value allocation problems result from both rational and biased asset valuation differences between providers and recipients. Third, monitoring and metering problems involve difficulties in writing and enforcing contracts over technological and commercial contingencies that can arise in dynamic and uncertain environments. Fourth, strategic problems arise from the rent dissipating effects of licensing to other firms and thereby creating new competitors in final product markets, or result from market power and small-numbers bargaining problems in markets for individual, idiosyncratic, and highly specific intellectual assets.

Anecdotal evidence suggests that all these types of problem exist in medical biotechnology. In relation to poorly defined boundaries among multiple separately assigned rights, Clarisa Long notes that search costs in medical biotechnology can be substantial.[9] For example, the prospective user of a patented research tool must begin by identifying and determining the scope of the relevant patent in order to decide what licence rights are needed.[10] To do this properly requires significant resources, and in any case cannot be conclusive because the patent situation in any given field is dynamic. If there are multiple patents in the field, the cost of deciding which ones are relevant to a particular avenue of research may itself be prohibitive.[11]

In an essay reporting insights derived from a 1997 National Institutes of Health (NIH) survey, Rebecca Eisenberg attributes value allocation problems in medical biotechnology to heterogeneities among institutions, exacerbated by uncertainty as to future technological development.[12] Institutions involved in biomedical research include universities, hospitals, private non-profit research institutions, government agencies, small biotechnology firms and major pharmaceutical firms; these institutions have different missions, resources and constraints.[13] The NIH survey found that all types of institution recognised that these differences might sometimes justify asymmetrical terms of exchange, but each felt that the asymmetry should work in its favour. The problem of bias is exacerbated in relation to research tools because their ultimate value depends on the outcome of future research, which cannot be predicted at the time of the transaction; this uncertainty brings the self-interested bias of negotiating parties into play as parties overvalue their own contributions to potentially profitable future discoveries at the expense of other inputs.[14] Although true uncertainty is not the same as a simple lack of information on the part of one or both parties to a transaction, it is clear that both types of uncertainty affect transaction costs: in most transactions, licensor and licensee have asymmetrical access to knowledge about the technol-

[9]Long (2000), pp.828-831.

[10]Long (2000), p.828. Cf Mandeville's discussion of licensing transaction costs, which is framed around Coase's categories of costs of arriving at an agreed price and costs of defining and enforcing obligations of parties to the agreement: Mandeville (1996), pp.70-71.

[11]Environment and Production Technology Division and International Food Policy Research Institute (2001), pp.22-23.

[12]Eisenberg (2001), p.235ff.

[13]Eisenberg (2001), p.235. See also Council on Governmental Relations (2001), pp.1-2.

[14]Eisenberg (2001), p.243.

ogy, and the risk of opportunism on the part of the better-informed party makes it more difficult for the parties to reach agreement.[15]

According to anecdotal evidence, monitoring and metering problems are particularly severe in medical biotechnology. Again, uncertainty – "a severe and intractable lack of knowledge on the part of all parties to the transaction regarding the fundamental value of the resource changing hands" – and heterogeneity of participants in transactions are the main contributing factors.[16] Uncertainty forces the parties to incorporate terms covering a wide range of possible contingencies, exacerbating the inherent complexity of most technology licensing agreements (see chapter 5, p.110). If the prospective user of a research tool must negotiate multiple licences, not only will the costs be higher because of the greater number of negotiations to be concluded, but the complexity of each negotiation will be increased because the licensee must avoid committing itself to terms in one contract which would prevent it from fulfilling the terms of another contract.[17] Further, recent research on the sociology of scientific exchange, described in chapter 2, suggests that the problem of uncertainty may arise not just in relation to the value of the resource changing hands, but also the very nature of the resource itself. Recall that the current sociological approach undermines the notion of research tools as discrete, well-defined entities, treating them instead as elements of a continuous data stream. For the purposes of an exchange agreement, the data stream must be divided into transferable portions, and though convention provides some guidance as to how these portions should be bounded, there are actually many possibilities, and therefore room for negotiation – and negotiation breakdown.[18]

With regard to the contribution of institutional heterogeneity to monitoring and metering problems, participants in the 1997 NIH survey felt that their counterparts in other sectors did not appreciate the difficulties they faced in complying with particular contract terms;[19] but heterogeneities exist within as well as among institutions in medical biotechnology.[20] For example, the interests of scientists employed by a university do not always coincide with those of the lawyers and businesspeople employed to negotiate contract terms of behalf of the institution. In general, academic scientists are mainly interested in acquiring needed research tools as quickly as possible, whereas it is the responsiblity of university technology transfer professionals to protect the university from incurring obligations which would limit funding or licensing opportunities or freedom to conduct future research.[21] Not only do these groups have different interests, they have different spheres of expertise and professional cultures which can lead to serious communication problems and sometimes to mutual hostility. Eisenberg

[15]Eisenberg (2001).
[16]Long (2000), p.834.
[17]Long (2000), pp.828-834 passim.
[18]Hilgartner & Brandt-Rauf (1994), p.362.
[19]Eisenberg (2001), pp.235-236. See also Heller & Eisenberg (1998), pp.700-701.
[20]Eisenberg (2001), p.239ff.
[21]Eisenberg (2001), pp.240-241.

notes that, in practice, scientists often choose to bypass their employers' official procedures and approach other scientists directly. She points to the emergence of a two-tiered market in research tools: in the official "proprietary" tier, technology transfer professionals engage in protracted haggling over contract terms, while in the unofficial "free exchange" tier, scientists deal with one another according to the rules of scientific etiquette relevant to the field.[22] Eisenberg's analysis resonates with Hilgartner's observations that access decisions are negotiated within research networks rather than made by individuals, and that audiences and markets for data do not necessarily consist of individuals or undifferentiated groups (see chapter 2, p.15).[23] Hilgartner also notes that rhetoric based on collective definitions of appropriate conduct can be important in shaping the outcome of negotiations.[24] In many cases shared norms may contribute to efficiency; certainly, Eisenberg takes the view that transaction costs are generally lower when like negotiates with like.[25] On the other hand, whether the fact of shared cultural norms is likely to lower or to raise transaction costs depends on the norms in question. For example, Stephen Maurer attributes the failure of an attempt between 1999 and 2001 by a group of academic biologists to establish an international mutations database to the fact that academic culture has no analogue to the norms that facilitate transactions in private enterprise.[26] Maurer refers specifically to the habit of deal-making, procedural norms such as meeting deadlines, sticking to decisions once made, settling disagreements by voting and limiting discussion to realistic proposals, knowing how to price things, willingness to think about business plans and commit time and energy to negotiations, and willingness to call on personal contacts in order to strengthen an agreement.[27] Labeling the failure a tragedy of the anticommons, Maurer suggests this example demonstrates the inability of the scientific community to conduct coherent negotiations.[28] It might be fairer to say that norms which are adaptive in one set of circumstances (such as the habit of constructing reasons why a particular project deserves funding at the expense of thinking about how the project can be marketed as a product) may be maladaptive when circumstances change, as they undoubtedly have done in academic biology with the spread of commercialisation.

Monitoring and metering problems include difficulties in enforcement as well

[22]Eisenberg (2001), pp.242-243. McCain has studied scientific etiquette surrounding the exchange of experimental materials, instruments and methods through interviews with experimental geneticists and by analysing acknowledgement patterns in published research papers. She identifies several factors which affect the behaviour and expectations of individuals as information requesters and information providers. (See generally McCain (1991).)

[23]Hilgartner & Brandt-Rauf (1994), pp.362-363.

[24]Hilgartner (1997), p.7.

[25]Eisenberg (2001), p.239.

[26]Maurer (2001), p.15.

[27]Maurer (2001), p.15. Maurer notes that two other issues that might have been expected to create obstacles did not arise, ie the community did not appear to have any ideological commitment to "op

en source" principles, and neither were members particularly concerned about "giving away" intellectual property.

[28]Maurer (2001), p.17.

as negotiations. Long points out that the costs of enforcing the terms of a licence and protecting against infringement by non-licensees may include substantial indirect costs: the perception of potential litigation imposes planning costs, discovery imposes opportunity costs, and news of a patent infringement suit generally causes both the patent holder's and alleged infringer's firms' values to drop.[29] Where an agreement for the transfer of proprietary research tools establishes an ongoing collaborative relationship, "enforcement" costs will also include the costs of maintaining the relationship and adjusting the terms of the agreement to changing circumstances.[30]

As for strategy-related bargaining problems, uncertainty again plays an important role by motivating parties to try to limit their exposure to risk. For example, a pharmaceutical firm intending to licence out a research tool for scientific use may be concerned that research conducted using the tool might lead to increased competition, undermine the firm's patent position or generate data that would trigger a tightening of regulatory requirements for its products.[31] In response it may seek to impose terms requiring the licensee to assign or licence any improvements back to the firm on an exclusive basis, requiring the licensee not to challenge the patent's validity or restricting the publication of research results produced using the tool. Other common terms include price and quantity and territorial restrictions, restrictions on sublicensing, and leveraging arrangements – for example, terms bundling patented and non-patented products together, extending the licence to territories in which the licensor has no intellectual property rights, or obliging the licensee to pay royalties until the last rights in a composite licence expire.[32] As Eisenberg points out, conflict over restrictive provisions can be particularly difficult to resolve where prospective users of multiple research tools face similar demands from several owners.[33]

Strategic maneuvering is not limited to formal negotiations among institutions. In a 1996-97 survey of US medical school faculty, Eric Campbell et al.[34] found that academic geneticists were more likely to be denied access to other academic investigators' data if they were young, primarily engaged in research, much published, actively commercialising their research, or were leaders in their field. While Campbell et al.'s results do not reveal the reasoning behind refusals to provide access, one interpretation is that professional jealousy increases the chances of bargaining breakdown in Eisenberg's "informal" transaction tier. In addition, researchers who had denied research results to others were more likely to have their own requests refused,[35] a finding that highlights the fact that each

[29]Long (2000), pp.830-831.

[30]Hilgartner makes this point in the context of collaboration agreements between scientists (Hilgartner (1997), p.5).

[31]Eisenberg (2001), p.244.

[32]Restrictive licence provisions have received attention in the literature on competition law and are also a topic of particular concern for developing countries licensing technology in from overseas. See, for example, Nielsen (2001), pp.12-13; Mandeville (1996), pp.71-73; Barton (1997a).

[33]Eisenberg (2001), p.230.

[34]Campbell et al. (2000).

[35]Campbell et al. (2000), p.305.

negotiation (formal or informal) within the kinds of research network that exist in biotechnology (see discussion of the "data stream" model in chapter 2, p.14 above) is not an isolated incident, but helps to shape the parties' ongoing relationship and their relationships with others in the network. A bad reputation earned in the course of one negotiation may adversely affect a party's success in later negotiations – although conversely, parties involved in an ongoing relationship may be more highly motivated to reach agreement in any given round of negotiations, both for the sake of maintaining the relationship and because concessions made in one round of negotiations may be recovered in the next.[36]

3.3.2 Has anticommons tragedy eventuated?

The foregoing discussion established that preconditions for anticommons tragedy do exist in medical biotechnology. We now turn to the question whether a tragedy of the anticommons has in fact eventuated in this field.

It is inherently difficult to conduct rigorous studies of bargaining breakdown in technology licensing markets for several reasons. Firms generally do not keep systematic records of projects stopped and the reasons for stopping them; even if such records did exist, these reasons are likely to be complex and difficult to ascribe to a single consideration such as difficulty in accessing intellectual property. Practical difficulties for researchers may also arise from the fact that the relevant information is likely to be commercially valuable and therefore kept confidential.

Nevertheless, several empirical studies have been attempted in the field of medical biotechnology. In 1997, the NIH study referred to in the previous section suggested that the problem of bargaining failure in the market for intellectual property licences was real. Eisenberg reported that for scientists, bargaining breakdown is evidenced by significant delays attending the outcome of negotiations over material transfer agreements (MTAs), patent licence agreements and database access agreements; for university technology transfer officials, by resource problems arising from the need to renegotiate previously routine agreements and the need to resist attempts by outside parties to impose increasingly onerous terms; and for private firms, by the growing administrative burden of conducting negotiations and by delays in research.[37]

At first glance, more recent studies appear to contradict this finding. A survey of studies conducted in the past two years of the United States, European and Australian industries reveals that despite proliferation of intellectual property rights, a tragedy of the anticommons has not yet eventuated in medical biotechnology.[38] This is not because transaction costs are low; as we have seen, there is considerable anecdotal evidence that transaction costs associated with the exchange of proprietary biotechnologies are substantial, and this is confirmed by the recent research. Rather, it appears that the value of many transactions is large

[36]This is the advantage of "repeat players" over "one-shotters" in litigation: Galanter (1974).
[37]Eisenberg (2001), p.225.
[38]Walsh & Cohen (2003), Straus et al. (2002) and Nicol & Nielsen (2003), respectively.

enough that they are not abandoned despite high costs. Instead, industry players have adopted various "working solutions" to keep the wheels turning, including taking licences (ie successful bargaining in spite of high transaction costs); inventing around patents; going offshore; infringement under an informal, legally unsanctioned "research exemption"; developing and using public databases and research tools; court challenges to patent validity; and mutual non-enforcement among members of particular research communities.

Should we be reassured by these findings that "the momentum of scientific research and discoveries in the biomedical fields remains strong and unencumbered"?[39] Not entirely. The authors of the US, European and Australian studies all acknowledge that many "working solutions" impose costs of their own, both private and social; these costs matter, for the following reasons.

First, as Eisenberg pointed out in relation to the NIH study, transaction costs are a greater obstacle to low value exchanges than to high value exchanges, for the simple reason that transaction costs eat into the surplus to be gained from an exchange: the smaller the surplus, the greater the risk of bargaining breakdown. The problem is that overall progress may depend heavily on the unfettered flow of low value exchanges of methods, materials and data, so that even if the value of each individual exchange foregone due to bargaining failure is low, the aggregate social value of these exchanges may be considerable.[40] In this context, the value of a transaction must be measured not only against the cost of the transaction itself, but against the cost of any "working solution" that might be adopted as a substitute. If the value is low, it is likely that not only will the transaction itself not take place, but there will also not be any cost-effective alternative path forward.

Second, the fact that working solutions impose significant costs means they may represent a serious drain on resources for some players, especially publicly funded and small non-profit research organisations which, as we will see, carry a disproportionate burden in relation to public interest research and development. Some strategies, such as building up a defensive patent portfolio so as to improve one's bargaining position, are simply unavailable to the smallest and poorest participants – or, importantly, would-be participants – in the biotechnology industry.

3.3.3 Intellectual property and global public health

Accepting that there is not yet any clear evidence for a tragedy of the anticommons in medical biotechnology, we turn now to the broader question of whether current intellectual property law and policy helps or hinders the contribution of biotechnology research and development to improved global public health.

For most people in the world today, health and life expectancy are affected by a range of complex issues to do with poverty, food insecurity and limited access to medical treatment. The issue of food insecurity is subsumed in the discussion of agricultural biotechnology later in this chapter, and most poverty-related health

[39]NIH Director's Policy Forum, "Introduction", http://www.nih.gov/about/forum/.
[40]Eisenberg (2001), p.234.

issues lie beyond the scope of this thesis. Thus, the rest of this section focuses on access to medical treatment. However, it should be noted that although access to medicines, including newly developed medicines, is important for health outcomes, it is in many cases less important than other factors. A well fed person with access to clean water and living conditions and to information about how diseases are spread is less vulnerable to most diseases even if there is no actual treatment in existence, as well as being less likely to die of simple starvation or exhaustion. For example, Richard Lewontin notes that the rise and fall in infant mortality in Brazil has been closely correlated with fluctuations in real wages rather than with the introduction of new medical treatments.[41]

To answer the question of what problems exist in relation to access to medical treatments and how they relate to intellectual property in biotechnology inventions, it is helpful to refer to the work of the Commission on Intellectual Property Rights (the Commission), which recently conducted a broad-ranging study of the global impact (costs and benefits) of intellectual property rights, particularly in the developing world.[42] Statistics quoted by the Commission demonstrate that developing country diseases are a huge problem in terms of global social welfare. Tuberculosis, malaria and HIV/AIDS (the biggest single cause of mortality in developing countries) together claimed nearly six million lives in 2002 and led to debilitating illness for millions more; there are also a large number of less common diseases that collectively affect large numbers of people.[43] Thus, developing country diseases are a very big problem in terms of global social welfare. For developing country diseases that are also prevalent in developed countries, such as HIV/AIDS and diabetes, research directed at developing country markets may produce appropriate treatments.[44] In such cases the problem is one of access (discussed below). For developing country diseases that are not prevalent in developing countries, or that commonly take a different form so that treatments designed for patients in developed countries would be ineffective, the problem is twofold: first, how to mobilise resources to develop treatments, and second, how to ensure access to treatments once developed.[45]

With respect to mobilising resources for research and development relating to developing country diseases, the evidence examined by the Commission suggested that intellectual property rights have little positive effect. In relation to the private sector, the explanation is that research and development activity is driven by profitability, which is largely determined by the size of the market.[46] The market for a drug must be significant before it is worth investing resources in research and development because of a high percentage of failures at each stage of the process, from identification of molecular targets to clinical trials. In the standard "blockbuster" business model, a few enormously profitable drugs

[41] Lewontin (1993), p.102.
[42] Commission on Intellectual Property Rights (2002).
[43] Ibid., p30.
[44] Ibid.
[45] Ibid., p.31.
[46] Ibid., pp.32-33 *passim*.

effectively subsidise all the others.[47] As the product life of each blockbuster can be extended only so far beyond the period of patent protection, and the outcome with respect to each new candidate is unpredictable, firms are unwilling to take on a project that does not promise at least the possibility of huge commercial success. The demand for medicines for diseases that are specific to or concentrated in developing countries is small in terms of market size because even though there are many sufferers, they have little capacity to pay; there is therefore little incentive for the private sector to develop medicines for this market. This is true not just for the private sector in developed countries, but also for the private sector, such as it is, in the developing world, which responds to the same incentives. As for the public sector, public sector institutions in the developing world have little capacity for pharmaceutical research and development, while the priorities of public sector institutions in richer countries are determined principally by domestic considerations.[48] (Although a number of recent initiatives aim to address this situation, their funding is insufficient given the scale of the problem).[49] Further, the evidence examined by the Commission suggested that any publicly funded research on developing country diseases that may be undertaken in developed countries may be adversely affected by restrictions on access to proprietary research tools – an anticommons effect. Thus, even though there may be no patent on any given research tool in a particular developing country, intellectual property rights in tools in developed countries may constrain research and development on developing country diseases. For all of these reasons, the Commission found that less than 5 percent of worldwide pharmaceutical research and development expenditure goes to finding treatments for developing country diseases.[50]

The second aspect of the problem described by the Commission on Intellectual Property Rights relates to ensuring access to treatments once they are developed.[51] In the Commission's view, access to the final products of biomedical research and development depends on two factors: affordability and the existence of a health service infrastructure that can support delivery. The evidence examined by the Commission suggested that the existence of intellectual property rights in medicines does adversely affect affordability. In developed countries, generic competition causes prices to fall quite sharply, particularly if the market is large enough to support a number of generic competitors, indicating that patents, while they are in force, keep the prices of drugs higher than they would otherwise be.[52] As to the developing world, although multinational drugs companies have not patented their products in all developing countries, patents can still affect prices in those countries because most low income developing countries rely on imports for their supplies, so that the existence of patents in potential

[47]Ibid., p.33.
[48]Ibid., p.32.
[49]Ibid.
[50]Ibid.
[51]Ibid., p.34ff.
[52]Ibid., p.36.

supplier countries may allow the patentee to prevent supplies being exported to other countries. From 2005, the benefit of transitional provisions of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) relating to the patenting of pharmaceutical products will cease.[53] This will affect major generic producers such as India. One solution would be for countries that currently import drugs to facilitate the growth of their own domestic generic industries, but in most cases, the Commission concluded, it would be difficult for such countries to create a competitive environment for patented and generic products because of the small size of their markets and lack of indigenous technological, productive and regulatory capacity.[54]

As to the second factor affecting access to existing drugs – availability of adequate health infrastructure – this factor has little to do directly with intellectual property rights, and the Commission noted that the pharmaceutical industry often argues that infrastructural problems are more important as constraints on access to medicines in developing countries than intellectual property issues.[55] The Commission's response was that there was no reason not to try to address both issues,[56] and that the cost of pharmaceutical products in developing countries is an important concern, particularly because most poor people in developing countries pay for their own drugs, which is not normally the case in the developed world (where costs are met mainly by the state or through insurance).[57]

To summarise, intellectual property rights in the products of biomedical research and development raise the prices of drugs by excluding generic competition, but do not stimulate the development of the most urgently needed medical treatments because the relevant markets are too small to be attractive to private sector players following a "blockbuster" business model, while public sector institutions either lack the capacity to conduct research and development or (in developed countries) are preoccupied with domestic needs. Thus, it is apparent that the biggest concerns raised by intellectual property rights in medical biotechnology lie beyond the scope of the empirical studies cited above (p.42). These studies are limited to reporting the experiences of current industry participants in developed countries entering negotiations over technological assets. They do not address the major structural problems of markets in medical biotechnology, and they do not take into account the views of those who are not able to participate in biotechnology research and development at all.

3.4 Agricultural biotechnology

This section addresses the same three questions as the previous section, but in the context of agricultural biotechnology rather than biomedicine: first, whether the

[53] Ibid., p.38.
[54] Ibid., p.37.
[55] Ibid., p.38.
[56] Ibid., p.39.
[57] Ibid., p.30.

necessary preconditions for a tragedy of the anticommons exist in agricultural biotechnology; second, whether such a tragedy has in fact taken place; and third, what are the greatest intellectual property-related concerns in this sector today in terms of global social welfare?

3.4.1 Preconditions for anticommons tragedy

Research and development in agricultural biotechnology relies heavily on access to multiple research tools.[58] One reason is that most agricultural biotechnologies are actually packages comprising multiple components. Transformation technology – the means by which foreign genes coding for desired traits are integrated into a plant genome, allowing the regeneration of whole genetically engineered plants from the transformed tissue – is a case in point.[59] An essential tool in both commercial crop development and experimental plant biology, transformation requires access to specific gene sequences and functional information, to a range of enabling technologies (including gene introduction methods, promoters and selectable markers), and to germplasm or cultivars into which the novel genes can be integrated.[60] Another reason why scientific exchange is especially important to the progress of research and development in this field is that agricultural biotechnology is not a single discipline: it combines resources from many areas of biology, including crop genetics, breeding, agronomy, pest control and agroecology in a criss-crossing of many data streams.[61] For these reasons, innovation in agricultural biotechnology is both cumulative, in the sense that each invention builds on previous inventions, and complementary, in the sense that each invention contains elements derived from more than one source.[62]

Not only does research and development in agricultural biotechnology rely on access to multiple research tools, but these tools are increasingly subject to proprietary controls. Changes in intellectual property laws outlined in the previous chapter (p.18) have strengthened protection for inventions in agricultural as well as biomedical biotechnology; stronger protection has made molecular biological techniques more profitable and therefore more widely used, which in turn has increased the demand for protection:[63] the annual count of applications filed

[58]Nottenburg et al. (2002), p.17.

[59]The process is explained in detail at the website of the University of California at Davis Center for Engineering Plants for Resistance Against Pathogens, http://ceprap.ucdavis.edu/Transformation/tranform1.htm, last visited 6 June 2002.

[60]Bennett et al. (2002), p.5.

[61]Graff & Zilberman (2001b), p.2.

[62]Nelson & Mazzoleni (1997), p.7.

[63]Graff et al. (2001), pp.19-20, summarising a presentation by Brian Wright. The magnitude of this trend is indicated by the dramatic increase in US patent applications for gene sequences from 4000 in 1991 to 500,000 in 1996, a result of US and European court decisions allowing the patenting of DNA sequences of unknown function: Blakeney (2001), p.120. Note that in December 1999, the United States Patent and Trademark Office issued interim guidelines (finalised in January 2001) that raised the bar somewhat in relation to the patent utility requirement for gene fragments: Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001). However, many consider the rules are still too lax.

and patents granted for agricultural plant biotechnologies in the US, Europe and Japan and under the Patent Co-operation Treaty has grown exponentially since the early 1980s.[64] Legal means of protecting intellectual property in agricultural biotechnology include patents, plant breeders' rights (in the US, Plant Variety Protection Certificates), trademarks, geographical indications, trade secrets and contracts, the first two categories being the most important: see chapter 5.[65] (The use of intellectual property in agricultural biotechnology can also be controlled by technical means, such as hybridisation and genetic use restriction technologies – GURTs – which render seed unsuitable for replanting or suppress the expression of introduced traits in saved seed.[66]) While legal rights are established by national legislation and court decisions, in practice their content is determined by international agreements, which in recent years have further encouraged the proliferation of strong intellectual property rights by requiring national governments to meet certain minimum standards of protection.[67] As a result of these trends, research tools in agricultural biotechnology are subject to numerous overlapping proprietary claims.[68] Depending on the complexity of a product, its development may involve the use of dozens of proprietary research tools; an often cited example is that of GoldenRiceTM, a genetically engineered rice variety developed using approximately 70 different patented technologies.[69]

Thus, researchers in agricultural biotechnology must coordinate numerous disparate property rights in order to obtain an effective privilege of use, and so the first condition stipulated by Heller as necessary to the creation of a tragedy of the anticommons is fulfilled.[70] There is also evidence that transaction costs associated with obtaining freedom to research and to commercialise the results of research in this field are mounting.[71] Indeed, streamlining access to patented technologies appears to have been a key motivation behind consolidation of a number of private agricultural biotechnology firms in the 1990s.[72] As in biomedical biotechnology, a primary reason for high transaction costs is uncertainty concerning the scope and validity of patents. For example, two early patents origi-

[64] Atkinson et al. (2003), Figure 1.

[65] See generally Blakeney (2001).

[66] Nottenburg et al. (2002), pp.3-4

[67] Blakeney (2001), pp. 127-129, discussing in particular: modifications to plant breeders' rights under the latest (1991) amendment to the Convention for the Protection of New Varieties of Plants ("UPOV Convention") which limit farmer's privilege, i.e. the right of a farmer to save seed from a first crop grown from purchased seed of the protected variety for use in sowing subsequent crops; and Article 27.3(b) of the World Trade Organisation (WTO) Agreement on Intellectual Property rights ("TRIPS Agreement") of 1994, which requires that WTO "Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof". The effect of TRIPS is that developing countries are no longer free to ignore the UPOV Convention limitation on farmer's privilege. See also Graff et al. (2001), pp. 19-20, summarising a presentation by Brian Wright.

[68] Nottenburg et al. (2002) , p.4.

[69] Nottenburg et al. (2002), p.17.

[70] Graff et al. (2001), p.18, summarising a presentation by John Barton.

[71] Graff & Zilberman (2001b), p.2.

[72] Graff et al. (2003b).

nally assigned to W.R. Grace & Co. would (as written) have given the company control over all genetically engineered varieties of cotton.[73] The scope of these patents was eventually narrowed following appeals and process; such reversals have been relatively common in agricultural biotechnology, and at times patent litigation has been rampant in the industry.[74] Similarly, a recent survey of intellectual property rights related to Agrobacterium-mediated transformation (a key enabling technology for plant transformation) concluded that ownership of the most far-reaching patents in this area cannot yet be determined because the broadest patents have yet to issue.[75] More subtle problems have also arisen, for example the use of licence provisions in which a firm's agreement to insert its genetic traits into a collaborating firm's germplasm prohibits any third-party genetic material from being inserted into the same germplasm. According to Greg Graff and Carol Nottenburg, high transaction costs associated with licensing intellectual property rights in agricultural biotechnology result from uncertainty of patent validity, excessive breadth of patents, conflicting claims of patents, difficulty of identifying valid licensors, the costs and slow pace of litigation and concern over liability, brand image and externalities control; in some cases, owners have been simply unwilling to negotiate with potential users.[76] Evidence of high transaction costs means that Heller's second condition is also fulfilled.

3.4.2 Has anticommons tragedy eventuated?

As with biomedicine, it is difficult to empirically assess the impact of proliferating intellectual property rights and high transaction costs in agricultural biotechnology because post-grant transactions cannot be tracked through publicly available information. The picture is further complicated in this field by the fact that the answer to the question whether anticommons tragedy has eventuated appears to be different for different sectors of the industry.

Until recently, nearly all agricultural research was conducted in the public sector. However, ownership of much of the intellectual property resulting from this research has been transferred to the private sector. For example, the survey of intellectual property rights in Agrobacterium-mediated transformation mentioned earlier found that although most of the basic research that led to the development of this important tool took place in public institutions, private sector entities now hold nearly all of the key patent positions. Although the remaining public sector intellectual property portfolio in agricultural biotechnology is still strong when

[73]Ibid., pp.6-7.

[74]Ibid.

[75]Roa-Rodriguez & Nottenburg (2004).

[76]Recent examples of hold-ups relate to the University of California's long shelf life tomato and Michigan State University's herbicide resistant turfgrass: Graff et al. (2001), pp.19-20, summarising a presentation by Brian Wright. Determining freedom to operate can be costly if analysis is referred to a lawyer and daunting for non-legal professionals due to the dynamic nature of patents, difficulties in claim interpretation, the cumulative nature of biotechnologies, the difficulty of searching patent literature, and frequently a lack of in-house infrastructure: Nottenburg et al. (2002), p.14.

taken as a whole, its ownership is highly fragmented among different institutions, which now appear to be experiencing classic anticommons effects. As in the case of biomedical research, the problem affects different types of institutions differently. With respect to licensing out of technologies in exchange for revenue, some institutions own very little intellectual property, while others may own substantial portfolios but face difficulties in relation to effective management and marketing. With respect to licensing in (i.e. gaining access to research tools owned by others) the clearest distinction is between research institutions in developed and developing countries. Researchers in developed countries are frequently under the misapprehension that they do not need to obtain permission to use other people's technology on the basis that they and their institutions are protected from any infringement action by a research exemption. In fact, while the extent and legal basis of any research exemption depends on national patent laws (which differ on this point), in practice research exemptions in developed countries tend to be quite limited; though in many cases the actual risk of being sued is still low, it is likely to increase as public and non-profit institutions form closer relationships with industry. By contrast, researchers in less developed countries are inclined to overestimate the risks associated with using other people's technology, which are often not patented in the relevant jurisdiction. However, parties' perceptions that a particular technology is owned by someone else who would object to its use can be as effective in constraining researchers' conduct as the legal reality, and in any case, perceptions and reality are likely to converge in the near future as developing countries implement their obligations under TRIPS and "TRIPS-plus" agreements.[77]

Meanwhile, the private sector agricultural inputs industry has undergone a startlingly rapid and comprehensive restructuring over the past two decades as chemical giants like Dow and DuPont moved aggressively into plant biotechnology and made huge investments in the life sciences, buying up all the larger national seed firms in North America and acquiring most surviving start-ups in the research-intensive agricultural biotechnology sector by the end of the 1990s.[78] The industry structure that has emerged is characterised by a very small number of tightly woven alliances, each organised around a major life sciences firm and vertically integrated from basic research and development through to marketing.[79] In this environment, new agricultural biotechnology start-ups are quickly integrated into the worldwide oligopoly once the promise of their technical innovations has been demonstrated, a pattern reminiscent of the computer software industry.[80] There is evidence that this consolidation has been driven primarily by the need to avoid high transaction costs associated with multiple intellectual property rights,[81] but whether or not intellectual property rights were a major causal factor, the outcome is certain: most key enabling technologies are now

[77]See generally Nottenburg et al. (2002).
[78]Graff et al. (2003b).
[79]Ibid.
[80]Wright (1998b).
[81]Ibid.

in the hands of only a handful of firms. To return to the plant transformation example mentioned above, Graff et al. show that by 1999, the top seven firms in the industry in terms of intellectual asset holdings controlled three-quarters of patents on transformation technologies and genetic materials, together with close to 100 percent of germplasm patents.[82] Similarly, in the previously mentioned survey of Agrobacterium mediated transformation, of 27 key patents in the crucial "vector" category, 26 were owned by three institutions; further, all of the patents on binary vectors (which largely supersede earlier vector technologies) were held by a single firm – Syngenta – that also held a dominant position in the "dicot" category (which includes most commercially important crop plants).[83] Moreover, although consolidation of intellectual property ownership appears to have reached its limit in relation to current technologies, it is likely that consolidation will increase rather than decrease with the emergence of new technologies.[84] Thus, in contrast to the public sector, no tragedy of the anticommons has eventuated in private sector agricultural biotechnology. Instead, private industry has side-stepped this outcome through an extreme form of a phenomenon described by self-described anticommons optimist, Robert Merges – the formation of transaction-cost-lowering institutions.[85] However, it would be surprising if such a high level of industry concentration had no adverse effects on innovation. Richard Jefferson argues that even the remaining companies and institutions are fighting over who owns the tools for gene technology instead of getting on with developing applications, to the point of "complete and total constipation",[86] while John Gale points out that companies are now pulling back from long-term investments in high-tech crop improvement.[87]

3.4.3 Agricultural biotechnology and food security

To what extent is the current mixture of anticommons tragedy and "institution-forming success" in the agricultural biotechnology industry a problem? For agricultural technology, as for biomedicine, the stakes are high: 780 million people in the developing world are currently suffering from malnutrition, a large proportion of them farmers who cannot grow, or sell, enough food to make ends

[82]Ibid., p21.

[83]Roa-Rodriguez & Nottenburg (2004).

[84]Graff et al. (2003a).

[85]Merges (2001), pp.129-130; see also Merges (1996) and Merges (2000). Merges argues that in some contexts where there are multiple owners and transaction costs are high, an anticommons tragedy may be avoided if communities of intellectual property owners develop collective institutions to lower the transaction costs of bundling multiple licences. Such institutions include copyright collectives in the music industry and patent pools in the automobile, aircraft manufacturing and synthetic rubber industries and, more recently, the consumer electronics industry. Merges sees these institutions as beneficial in their own right, observing that they provide a framework for standardisation of techniques and for the institutionalised exchange of unpatented technical information – advantages which might not be realised in the absence of strong property rights: Merges (2001), p139 (cf Mandeville (1996), discussed in chapter 2 above).

[86]O'Neill (2003), p.22.

[87]Knight (2003).

meet.[88] While scientific progress, including in biotechnology, cannot solve this problem on its own, it certainly has the potential to make a difference. Agricultural innovation is important not just because it can create dramatic gains in production and productivity (as, for example, during the "green revolution" of the past four decades, discussed further below), but because it stimulates broader economic growth that can help break the cycle of poverty and food insecurity.[89] It has been suggested that innovations in agricultural biotechnology, being embodied in seeds, are uniquely well suited to attack agronomic and environmental problems in economically and technologically less developed areas.[90]

As in biomedicine, current research and development priorities in agricultural biotechnology reflect the needs of large commercial operations targeting big markets. From a social welfare perspective, what is needed are traits and crops that are useful to small subsistence farmers. Relevant traits include those that increase yield potential, increase the stability of yields through resistance to biotic and abiotic stress, or enhance farmers' ability to grow subsistence crops in difficult environments (for example, drought and salinity); currently available genetically engineered traits, such as herbicide tolerance, are not so useful to poor farmers. Relevant crops are the basic staples of the poor, such as rice, wheat, white maize, cassava and millet.[91]

Although there is a general consensus as to what kinds of agricultural biotechnology research and development are most likely to benefit poor people in developing countries, it is less clear who might conduct such research. Not all developing countries are in a position to conduct their own agricultural research and development. For example, Carl Pray and Anwar Naseem categorise developing countries according to their biotechnology and seed research capacity.[92] At one end of the spectrum, some countries – including China, India and Brazil – have the capacity to do independent biotechnology research, a strong plant breeding capacity using international agricultural research centres as sources of germplasm, and in some cases also strong private sector seed companies and a working system of biosafety regulation. Countries at the other end of the spectrum have only limited conventional plant breeding capacity, and no capacity for biotechnology research at all. In the poorest countries the problem is not so much a lack of access to proprietary technologies as a lack of research capacity,[93] but in

[88] Anonymous (2001).
[89] Pray & Naseem (2003).
[90] Graff et al. (2003a).
[91] Pray & Naseem (2003).
[92] Ibid.
[93] Researchers in less developed countries are inclined to overestimate the risks associated with using other people's technology: Graff et al. (2001), p.18, summarising a presentation by John Barton. Nottenburg et al. report a common misconception that a patent awarded in one country confers property rights in all countries: Nottenburg et al. (2002), p.5. In fact, the cost of obtaining protection in many different countries is such that most inventions are patented in just one or a few developed countries with large markets: in 1998, the number of patents granted in the US, Europe and Japan accounted for about 80 percent of the world's patents, and it is likely that most of the remainder were also granted in developed countries: Nottenburg et al. (2002), p.5. Al-

developing countries with intermediate or advanced agricultural research capacity, access to proprietary technologies is an issue. This is because, as noted above in section 3.4.2, both public and private institutions in developing countries are often reluctant to use technologies without explicit permission from their owners. Reasons include a desire either for long-term collaboration with the technology owner or to export products of the technology to developed countries where patents do apply. Thus, in general, developing countries themselves conduct very little agricultural research and development aimed at meeting the needs of their own poor, and this is especially true in relation to biotechnology research.[94] Meanwhile, in developed countries the amount of public funding devoted to research relevant to poor farmers in developing countries has been stagnant or declining since the 1960s. For example, funding for the Consultative Group on International Agricultural Research (CGIAR), provided by a predominantly first world donor community, has fallen in real terms since 1990 to the extent that both its research efforts and its ability to maintain valuable gene banks held by several of its sixteen independent Centres are now under threat.[95] The effects of this decline in funding are exacerbated by anticommons effects experienced by public sector researchers in developed countries, who might otherwise be in a position to innovate on behalf of the poor in developing countries.[96]

As to developed countries, over the past few decades, the decline in public funding for agricultural research has been accompanied by a rapid growth in private investment, especially in Europe and North America. Private sector research, supported by intellectual property protection and sustained by demand from farmers in developed countries and the commercial sectors of a few of the richer developing countries, is now the dynamic element in agricultural research and development.[97] However, as with biomedicine, the private sector has little interest in developing crops for which there is no substantial market, whether they be minor specialty crops in the developed world or major staple crops in the developing world. Thus, the shift in balance between public and private sectors

though problems might theoretically arise with regard to technologies destined for crops grown in developing countries if those crops were subsequently exported to countries where the relevant intellectual property is protected, it has been shown empirically that exports from developing to developed countries are generally dwarfed by production and consumption in the developing world and that the value of these exports is concentrated in a few crops and a few exporting countries.Environment and Production Technology Division and International Food Policy Research Institute (2000) Thus, researchers in less developed countries are probably not seriously constrained by intellectual property considerations in the strict legal sense. (Depending on the manner in which developing countries choose to implement their obligations under TRIPs, this may soon change: in many developing countries, new patent laws are starting to come into effect such that technologies previously legally available to researchers in those jurisdictions will be protected: Nottenburg et al. (2002), p.32; Graff et al. (2001), p.18, summarising a presentation by John Barton, and p.34. (For a detailed discussion of TRIPS obligations relevant to agricultural biotechnology, see Barton et al. (1999).)

[94]Pray & Naseem (2003).

[95]Commission on Intellectual Property Rights (2002), pp.67-68; Pray & Naseem (2003), pp.4-10 *passim*; Anonymous (2001).

[96]Graff et al. (2003a); Wright (1998b).

[97]Pray & Naseem (2003), pp.8-9.

in agricultural research means that commercial interests rather than food security needs are driving the current research agenda.[98] Consolidation of the agricultural industry, described above, aggravates this situation by raising barriers to entry for smaller players who might be interested in serving markets that are too small to be attractive to agronomic systems giants like Monsanto.[99] Further, a reduction in supplier numbers may elevate the costs of doing research, making it even harder for players in developing countries or public sector institutions in developed countries to undertake research and development on behalf of the poor, as well as more difficult for any organisation (private or public) to deliver agricultural inputs at reasonable prices that poor farmers can afford.[100] Another concern that arises out of the dominance of agricultural research and development by big private sector firms relates to the need to maintain agricultural biodiversity, both for the sake of the environment and for food security. The legacy of the green revolution includes widespread adoption of monoculture-based farming practices that threaten the diversity of genetic resources.[101] This problem is exacerbated by declining funding for the CGIAR, which plays a crucial role in guarding diversity by maintaining its own gene banks and assisting in the maintenance of collections owned by developing countries, and by the evolution of intellectual property norms that make traditional agricultural practices such as the saving of seeds more difficult.[102] Finding a way to help poor farmers continue to preserve genetic resources is thus important not only for ethical reasons, but also for the future of agricultural innovation in both developing and developed countries.

An associated problem arising from the concentration of agricultural research and development in the hands of a small number of multinational firms relates particularly to biotechnology and is essentially a problem of conflict of interest. Most genetic engineering is carried out by private sector companies in industrialised countries. To the extent that biosafety concerns in connection with genetic engineering are scientifically justified,[103] concentration of the capacity to conduct biotechnology research in the hands of those who stand to gain from commercialising such research – quickly, cheaply and with minimal regulatory interference – is unlikely to lead to satisfactory outcomes.

In the longer term, academic researchers who cannot gain access to state-of-the-art technologies risk falling behind their commercial counterparts; this may reduce the rate of innovation in basic science and, in turn, the rate of development of commercial applications, in effect killing the goose that laid the golden egg.[104] Another way to express the same idea is that all types of organisation – from large

[98]Wright (1998a); Atkinson et al. (2003); Graff et al. (2003a); Pray & Naseem (2003); Anonymous (2001).

[99]Commission on Intellectual Property Rights (2002), pp.74-5.

[100]Wright (1998a); Pray & Naseem (2003); Commission on Intellectual Property Rights (2002); Knight (2003), quoting Gary Toennissen of the Rockefeller Foundation.

[101]Commission on Intellectual Property Rights (2002), pp.68-69.

[102]Ibid.

[103]For a detailed peer reviewed scientific listing of biosafety risks, see Scientific Working Group on Biosafety (1998).

[104]Graff et al. (2003a).

corporations, through small private sector innovators, to university and other public sector institutions – have a unique contribution to make to the progress of agricultural science and technology. Consistent with theoretical perspectives examined in chapter 2, empirical studies of the sources of biological innovation in agriculture show that the robustness of technology development over time depends on the participation of all institutional types.[105]

3.4.4 Summary

So far we have seen that in both medical and agricultural biotechnology, recent proliferation of intellectual property rights, together with difficulties in transferring those rights, has led to concerns about an impending "tragedy of the anticommons".

Available empirical evidence suggests that anticommons tragedy has not yet eventuated in medical biotechnology due to the adoption of various working solutions by industry participants. However, such solutions are beyond the reach of many industry participants and, importantly, would-be participants. This is a problem because, as we saw in section 3.3.3, a review of the impact of intellectual property rights on access to medicines among the poor in developing countries – that is, most of humanity – reveals that only a tiny percentage of worldwide pharmaceutical research and development expenditure is dedicated to finding treatments for developing country diseases, while at the same time, use of intellectual property rights as a means of excluding competition by generic drug manufacturers drives up the prices for treatments that already exist.

In agriculture, empirical evidence suggests that public sector researchers in developed countries are affected by a tragedy of the anticommons. Meanwhile, the private sector has avoided this outcome only at the cost of a radical restructuring that has dramatically reduced competition within the industry. As a result, smaller markets in developed countries are likely to go unserved because there are insufficient incentives to conduct research and development directed at such markets. However, a more serious consequence is that the combination of public sector anticommons tragedy and private sector concentration exacerbates the neglect of agricultural research and development conducted for the benefit of poor people in developing countries. The immediate result is continued poverty and hunger for many millions of people around the world. In the longer term, this situation threatens genetic diversity, undermines effective biosafety regulation and may hinder the overall progress of science and technology in this field.

3.5 Solutions

In this section we look at a number of proposed solutions to the problems described in the previous section.

[105]Graff (2002), pp.17-18.

3.5.1 Law reform

One class of proposed solution aims to address these problems by fine-tuning domestic intellectual property and competition laws in both developed and developing countries. In intellectual property, the objective would be to stop the proliferation of intellectual property rights by redesigning the rules surrounding their inital grant. For example, John Barton argues that in the United States the notion of utility could be tightened to restrict patenting of fundamental concepts, that novelty and non-obviousness requirements should be interpreted more strictly, that the "experimental use" defence to patent infringement should be expanded and that automatic royalty-free licences, or at least compulsory licences at a reasonable royalty rate, should be issued for the use of any patented technology in research where the patent holder is not already making the technology sufficiently available.[106] Maureen O'Rourke goes further, proposing the introduction of a "fair use" defence to patent infringement similar to that available under copyright law.[107] In the developing world, the Commission on Intellectual Property Rights recommended that countries that do not yet have patent systems should consider carefully how particular implementations would affect innovation targeted at their specific needs.[108] In both developed and developing countries, competition laws could be used to respond to high levels of industry concentration.[109]

Even though the availability and scope of patent protection is determined by national laws, specific features of domestic legal regimes do have an impact beyond national borders: for example, as we saw earlier, patent rules applying in developed countries affect developing countries because much research relevant to developing countries may be carried out in developed countries or in collaboration with developed country researchers. However, one disadvantage of approaches involving fine-tuning of domestic laws is that such changes increasingly cannot be made in isolation from the international system. This system is still evolving, and ensuring the legitimacy and appropriateness of standards to be adopted requires active participation from all affected countries.[110] Unfortunately, many countries – especially developing countries – experience serious obstacles to participation, due to a lack of expertise, experience and familiarity with technical issues discussed in such international fora as the World Intellectual Property Organisation and the TRIPS Council, together with an inability to access unbiased external advice.[111] Even aside from these handicaps, many coun-

[106]See Barton (2000) and Barton (2001); see note 63 above regarding revision of the United States Patent and Trade Mark Office examination guidelines.

[107]O'Rourke (2000).

[108]Commission on Intellectual Property Rights (2002), p.25 and p.148.

[109]Ibid., Executive Summary.

[110]Commission on Intellectual Property Rights (2002), p.164.

[111]The Commission has made specific recommendations directed at improving WIPO's sensitivity to the needs of less developed countries, ensuring the appropriate timing of TRIPS-related obligations, avoiding pressure by developed countries on developing countries to adopt standards or timetables beyond those required by TRIPS (i.e. "TRIPS-plus" agreements), improving representation of developing countries in the evolution of international IP rules, and addressing

tries – both developed and developing countries – that are net importers of intellectual property and might therefore benefit from a weaker intellectual property regime at the international level suffer from a simple lack of bargaining power in negotiations with, in particular, the United States. This problem is exacerbated by the fact that both international and domestic law-making bodies may be subject to capture by powerful vested interests that favour a strong intellectual property regime.

In this connection it is worth noting that the strengthening of intellectual property rights in biotechnology over the past two decades has not been an isolated event; similarly, doubts about the desirability of stronger intellectual property rights have not been confined to the arena of life sciences research and development. Until recently, resistance to across-the-board privatisation of intellectual assets has been largely piecemeal and ad hoc, but in the past few years intellectual property skeptics have sought ways to bring conceptual unity to this resistance.[112] An emerging literature on the public domain draws on a number of different strands of literature dealing with intellectual property, including both literature on biotechnology research tools surveyed in the previous chapter of this thesis and literature on the open source movement referred to in later chapters.[113] This new "public domain" or "commons" movement combines theory with activism; one of its strengths is its incorporation of both top-down and grassroots approaches to dealing with the adverse impacts of intellectual property rights on ongoing innovation.[114] Initiatives associated with this movement include the "Creative Commons" initative at Stanford University, which makes good use of Internet technology and has proved effective in promoting a more open approach to a range of copyrighted works (especially music and weblogs) using standardised, user-friendly copyright licences that reserve some rights to the author while waiving others in favour of broad freedom of use.[115] In the scientific sphere, Jerome Reichman and Paul Uhlir have proposed a "contractually reconstructed e-commons for science and innovation",[116] while the Creative Commons' "Science Commons" initiative is due to launch in January 2005.[117]

certain substantive issues in periodic reviews of TRIPS. The Commission has also recommended support for further research to determine the costs and benefits of IP rights on both developed and developing countries: Commission on Intellectual Property Rights (2002), pp.155-168 passim; see also Drahos (2002).

[112]Boyle (2001).

[113]See generally Conference on the Public Domain, November 9-11, 2001, Duke Law School: http://www.law.duke.edu/pd/; in relation to scientific issues specifically, see Symposium on the Role of Scientific and Technical Data and Information in the Public Domain, 5-6 September 2002, National Academies of Science, http://www7.nationalacademies.org/biso/Public Domain Symposium Announcement.html and International Symposium on Open Access and the Public Domain in Digital Data and Information for Science, 10-11 March 2003, UNESCO, Paris, http://www.codata.org/03march-intlsymp.htm.

[114]For links to a number of activist organisations, see Open Source Biotechnology Project website, http://rsss.anu.edu.au/ janeth/Law.html#40.

[115]Creative Commons World Wide Web address: http://creativecommons.org/.

[116]Reichman & Uhlir (2002).

[117]"The mission of Science Commons is to encourage scientific innovation by making it easier

3.5.2 Increased public funding

Another problem-solving approach aims to redress the decline in funding for public research and development, while shaping more effective policies to direct that funding towards priority areas. In the agricultural arena, Pray and Naseem argue that achieving better funding for priority research would require the development of groups prepared to lobby on behalf of the poor, supported in local areas by anti-poverty groups and donors committed to reducing poverty.[118] In the pharmaceutical sphere, a proposed "World R&D Treaty" is based on the idea that if drug prices did not have to cover the costs of research and development, there would be no need for intellectual property protection on drugs: instead, knowledge about the manufacture of drug compounds could be in the public domain and drugs could become a freely traded commodity, resulting in lower prices.[119] Under the proposed treaty, the funds needed for pharmaceutical research and development would be raised by obliging countries to fund research and development up to a certain percentage of GDP, replacing current trade rules containing detailed specifications of intellectual property rules; countries could then decide if they wanted to follow a strictly closed system (with high drug prices for 20 years under patent rules), or experiment with open development models (discussed in detail in later chapters of this thesis).

3.5.3 Reducing transaction costs

Other approaches to preventing or countering anticommons tragedy focus on ways of reducing the cost of transactions aimed at co-ordinating multiple technology components, ranging from (external) market exchange of specific assets to (internal) integration of assets within a firm. As demonstrated by the experience of the agricultural biotechnology industry, described above (p. 50), some of these mechanisms can facilitate anti-competitive behaviour. However, not all transaction cost-lowering institutions pose an undue threat to competition. In the context of plant biotechnology, Nottenburg et al. put forward a range of options whereby public and non-profit institutions can gain access to proprietary research tools, including cross-licensing, obtaining low cost research-only licences, market segmentation, scaled licence fees, mergers or joint ventures with owners of research tools, direct funding from the private sector, alliances within the non-profit sector, obtaining joint grants of freedom to operate and collective rights organisations.[120] Each option has associated advantages and disadvantages. The option of forging mergers or joint ventures with private sector owners of research tools is examined in more detail by Pray and Naseem, who draw on past expe-

for scientists, universities, and industries to use literature, data, and other scientific intellectual property and to share their knowledge with others": http://science.creativecommons.org/, last accessed 17 December 2004.

[118] Pray & Naseem (2003).

[119] Hubbard (2003).

[120] Nottenburg et al. (2002).

rience to identify elements of successful private-public collaborations, as well as actions governments can take to facilitate such joint ventures.[121] In relation to the option of obtaining direct programmatic funding from the private sector, Pray and Naseem also identify a number of incentives that might motivate private sector players to make such funding available, together with possible government actions to promote this outcome. The option of forging alliances within the non-profit sector is well illustrated by the case of the Centre for Application of Molecular Biology in Agriculture (CAMBIA), an Australian-based non-profit research institute which aims to "invent around" key enabling proprietary technologies in order to make alternatives available to public and non-profit research organisations on an ability-to-pay basis.[122] Until recently, CAMBIA also provided a publicly accessible intellectual property resource ("CAMBIA IP") that aimed to help lower transaction costs by making patent searches and other intellectual-property related information-gathering easier and cheaper; this resource has now been subsumed by another initiative, described in chapter 7 (section 7.3.1, p.219). Once alliances within the non-profit sector have coalesced, suggest Nottenburg et al., they can then enlist the help of funding bodies to apply political pressure for concessions to non-profit organisations. Funding bodies such as the National Institutes of Health have substantial power to influence bargaining behaviour that has not yet been fully harnessed, though funding agencies (both public and private) have been behind a number of iniatitives to promote sharing in biotechnology research and development (for example, the Wellcome Trust was the linchpin in negotations to establish the SNP Consortium: see chapter 6, 156).

3.5.4 Collective rights organisations

The final option suggested by Nottenburg et al., that of forming collective rights organisations, has been explored in some detail by several authors and has been partially implemented in the agricultural biotechnology context (below,this section). Collective rights organisations can perform a range of functions, including that of assembling useful bundles of intellectual property rights belonging to members and possibly also non-members. Examples include the Global Biocollecting Society, analogous to collecting societies that already exist in the copyright arena, proposed by Peter Drahos to help overcome problems of uncertainty and enforcement confronting life sciences companies and indigenous groups contracting over the use of knowledge relating to plant material.[123] The most highly developed proposal for a collective rights organisation relevant to biotechnology research and development is in agricultural biotechnology, and is based on the "intellectual property clearinghouse" concept developed by Greg Graff, David Zilberman and others.[124] The Public Intellectual Property Resource for Agriculture (PIPRA) was jointly launched in 2003 by a number of public sector institu-

[121] Pray & Naseem (2003).
[122] See http://www.cambia.org/.
[123] Drahos (2000).
[124] Graff & Zilberman (2001a); Graff & Zilberman (2001b).

tions in the United States.[125] If successful, such a collective intellectual property management regime would enable an effective assessment of freedom-to-operate issues and could begin to overcome the fragmentation of public sector intellectual property ownership in agricultural biotechnology, while at the same time improving public-private sector interactions by better identifying collective commercial licensing opportunities. As those involved in establishing PIPRA could attest, the greatest difficulty in establishing successful collective rights organisations is that of fostering trust and confidence among potential members and users.[126] The danger is that more powerful players within the group will "hijack" the organisation and steer it in a direction that does not benefit the majority of members. The problem of hijacking is discussed further in chapters 4 and 5.

3.6 Participatory research and development

We have seen that very little biotechnology research and development is currently directed to where it is most needed, and that part of the answer may be for governments or other powerful institutions such as funding agencies to identify areas of need and consciously direct research and development towards those areas. However, possibly a more fruitful approach is to enhance participation in biotechnology research and development by those with the greatest need; of course, this is an important motivation behind efforts, described above, to lower the costs of intellectual property-related transactions and thence the barriers to participation in biotechnology research and development by less well-resourced entities. A prime example of the participatory approach is "participatory agricultural research" or, more narrowly, "participatory plant breeding" (PPB).[127]

The principal objective of PPB is to create more relevant technology and more equitable access to technology in order to improve the service and delivery of crop improvement research to the poorest and most marginalised people and areas. Secondary objectives include cutting research costs, affirming local people's rights over genetic resources, producing seed, building farmers' technical expertise and developing new products for niche markets (for example, organic foods). PPB works by developing and distributing locally adapted technologies as well as by supporting local capacity for generating such technologies. Implementations of this approach are diverse, but in essence, PPB involves clearly identifying farmers' needs and preferences and the reasoning behind them so that farmers are treated as partners in research: most research is conducted in farmers' own fields with farmers and researchers working side by side. The point is to introduce a

[125] Bennett et al. (2002).

[126] Rex Raimond, personal communication.

[127] See generally Thro & Spillane (2000); CGIAR Systemwide Program on Participatory Research & Gender Anlaysis, http://www.prgaprogram.org/index.php?module=htmlpages&func=display&pid=9, last accessed June 1 2004; *Seeds that give: participatory plant breeding* (2002), International Development Research Centre, http://web.idrc.ca/en/ev-30549-201-1-DO_TOPIC.html, last accessed 1 June 2004.

user perspective into adaptive research, bringing users into the early stages of technology development as both researchers and decision makers who help set priorities, define criteria for success, and determine when an innovation is ready for release. The application of PPB has so far been limited to the development of conventional technologies, but its potential in the biotechnology context is well recognised.[128]

The ideal of PPB for biotechnology research and development exemplifies a broader philosophy of participation and empowerment in relation to biotechnology innovation that is being more frequently articulated as the disadvantages of the current system become apparent. This philosophy was neatly expressed in a 2003 communique issued by scientists attending the XIX International Congress of Genetics in Melbourne, Australia:

> Fifty years since the double helix structure of DNA opened our eyes to new means of using genetics to contribute to human wellbeing, we are increasingly faced with the challenge of ensuring that the next fifty years delivers these benefits to all peoples... . The choices people are being given today seem not to be the choices people want... . The voices people hear today seem not to be the voices people trust or wish to hear. ... GM [Genetic Modification] technologies offer great potential to contribute to the production of foods people want... produced by stewards of the land under local oversight. [They] could also be the building blocks of new toolkits that encourage and empower creativity and entrepreneurship among the disenfranchised. Our vision of how this potential will be realised requires changes in the status quo. We see democratisation of innovation, including genetic modification, to be essential.... This is particularly urgent in poorer parts of the world that have yet to experience equitable development.... We believe it is essential to empower innovators everywhere, small and large, in public and in private sectors, by ensuring their access to enabling technologies.... The answers are ... in encouraging local capacity to innovate and respecting local choice of technologies. The freedom to innovate must not be hindered by barriers imposed by any interest group. To do so would be disrespectful of the legitimate drive of all people to solve their own problems. These barriers include... restrictive ownership of enabling technologies.... The right to innovate must not be the sole province of the highly capitalised, nor of a few owners of key intellectual property, who could thereby control, direct or limit innovation globally. ... The tools of innovation must not be withheld.[129]

[128]Thro & Spillane (2000).

[129]GMO Communique, XIX International Congress of Genetics, Melbourne, Australia, July 6-11, 2003: available at http://www.geneticsmedia.org/gmo_communique.htm, last accessed 18 December 2004.

3.7 Conclusion: the need for a biotechnology tool kit

In this chapter we have seen that essentially the same sequence of cause and effect operates in both medical and agricultural biotechnology. In both fields, the ability to conduct research and development depends on access to a full set of enabling technologies, analogous to the basic toolkits needed for cooking, gardening, sewing or any of a thousand other familiar productive activities. The fact that the elements of these toolkits are protected by intellectual property rights instead of being available in the public domain has two consequences.

First, intellectual property protection means that putting a toolkit together requires more resources, not only because of the need to provide owners of individual tools with some return in exchange for granting access, but more fundamentally because the very fact that the tools are owned gives rise to search, negotiation and enforcement costs that would not otherwise exist. This need for extra resources in turn has several consequences. One is that low value exchanges are less likely to occur, an undesirable outcome because most socially valuable innovation in fact takes place in small increments rather than in "great leaps forward" – in other words, high value data streams are disrupted. Another is that public and private resources that might otherwise have been devoted to research and development are wasted, just as energy in an engine is lost as heat due to friction. Finally, the more resources that are required in order to engage in innovative activity, the smaller the number of people or organisations that are willing and able to participate. (In medical biotechnology the number of players that can still afford to participate is still somewhat larger than in agricultural biotechnology, but the same selective pressure operates in both areas.) As we saw in chapter 2, scientific and technological problem solving proceeds most efficiently when carried out by many different actors working independently. A reduction in the number of participants in biotechnology research and development can therefore be expected to hinder the rate of innovation in relation to any given technology and is also likely to raise the total cost of production, leading to delays and higher prices for products and reinforcing the inadequacy of incentives to develop products for smaller markets. Further, a smaller pool of participants in biotechnology research and development means a reduction in diversity, leading to potentially serious blind spots in dealing with this powerful new technology. Because participants are effectively selected on the basis of wealth and are generally free to follow a more or less self-interested agenda, such blind spots are likely to cover exactly those areas of research that would be most useful to those most in need.

The second major consequence of granting intellectual property rights in elements of the basic biotechnology toolkit is reduced competition at the next stage of development as tool owners impose reach-through conditions on the products of research and development conducted using their tools. This reinforces existing market power and drives up prices for end products. As an example, consider the pharmaceutical industry case. Patents on the actual therapeutic molecules that are used as drugs allow pharmaceutical companies to exclude competition from generic drug manufacturers selling the same molecule, however it is produced.

This is consistent with the traditional monopoly-in-exchange-for-disclosure rationale behind patent protection. Very broad patents on drugs cover a much larger class of related molecules that might be shown to have therapeutic activity. Although more of a stretch, this is also consistent with the traditional patent rationale. However, if a pharmaceutical company also holds patents on one or more essential elements of a basic research and development toolkit, it will also be in a position to prevent competitors from "inventing around" its other patents to produce an equivalent treatment based on a different class of molecules. Any new treatments that might be developed by non-competitors (for example, university researchers) it can acquire on favourable terms instead of on the open market where it would need to outbid generic manufacturers as well as other brand-name companies. This is not consistent with traditional patent justifications, which often allude to increased incentives to others to invent around a patent as a reason for granting the patent in the first place – and the result is unnecessarily high prices for individual consumers or procurers. This is not to say that in the absence of patents on elements of a biotechnology toolkit, drug prices would be negligible. Considerable expense is inherent in producing a new drug. This is partly due to research costs – the costs of target identification, screening candidate molecules and pre-clinical testing in relation to many potential drugs that never make it out of the laboratory – and partly due to the need for extensive clinical trials to ensure product safety. However, many big pharmaceutical companies spend enormous additional sums on paying large executive salaries and maintaining their market position through, for example, lobbying and advertising (largely to doctors), yet still manage to routinely extract huge profits from sales. These are expenses for which the rest of society may prefer not to foot the bill.

Different solutions canvassed in the previous section target different links in this causal chain and each has its own advantages and disadvantages. Proposed solutions aimed at halting the proliferation of intellectual property rights are very important because of constant opposing pressure to "enclose" more and more of the public domain. However, even apart from the difficulty of persuading the guardians of the status quo that change is necessary and desirable, unless such solutions are expected to operate retrospectively they would have no immediate effect on the more proximate cause of problems in the biotechnology industry – that is, the lack of an affordable, accessible, unencumbered toolkit. Proposed solutions aimed at producing such a toolkit include efforts described above to obtain public funding for inventing around proprietary tools (in principle, such funds could also be obtained through private donations) and initiatives to "package" existing tools owned by several different players for easier access. Funding the production of a full toolkit is probably beyond the resources of any single player – even supposing every technology in the proprietary toolkit were technically substitutable – especially considering that maintaining an up-to-date collection of tools would involve ongoing expense. Moreover, a single entity might find it difficult to harness the full creativity of the biotechnology research and development community. On the other hand, co-operation among diverse players

is difficult to establish and maintain because of problems of trust and confidence arising largely out of a fear of technology "hijacking".

It is apparent from the foregoing discussion that attempts to overcome intellectual property-related problems in the biotechnology industry would be aided by some mechanism for producing a biotechnology toolkit that is both unencumbered and affordable (in terms of price and accessibility) even to the smallest players. Ideally, such a mechanism would not rely on law reform, reversal of current intellectual property policy or the co-operation of players who benefit from the status quo; it would allow the necessary innovation to draw on diverse funding sources and be distributed across many institutions; it would allow for incremental improvements to the elements of the toolkit over time; and it would provide contributors with some protection against hijacking of the evolving technology.

In fact, such a mechanism already exists outside the biotechnology industry in the context of computer software development. Known as "open source" licensing, it is described in detail in the next chapter.

Chapter 4

An introduction to open source

4.1 Introduction

In chapters 2 and 3, we saw that efficient technological innovation directed towards goals that serve the public interest depends on the unfettered exchange of information and materials among diverse participants, but that in biotechnology, intellectual property rights introduce friction that threatens to block important exchanges and exclude all but a small number of organisations (mainly large private sector firms) from helping to shape the direction of future research and development.

The situation described in chapters 2 and 3 has strong parallels with developments in the computer software industry over the same period. In both industries, a few corporations achieved tight control over key technologies, including important development tools, through aggressive use of intellectual property rights. However, in recent years the software industry has seen the emergence of an alternative mode of intellectual property management that has helped make software tools accessible to a much wider range of developers, from large corporations competing with the industry leaders to smaller developers and non-profit organisations. As foreshadowed at the end of the previous chapter, this had been achieved by the introduction of development toolkits on terms that enforce sharing and resist proprietary control.

Later chapters of this thesis explore the possibility that an analogous approach might offer at least a partial solution to intellectual property-related problems in biotechnology research and development. This chapter discusses open source software, giving a brief history of the open source software movement, an overview of how open source development works in the context of the programming community, a description of the terms with which software licences must comply in order to be certified as open source licences, and a summary of the analytical framework to be used in subsequent chapters.

4.2 A brief history of open source software

To understand what is meant by "open source" software, it is helpful to consider the conventional approach, sometimes referred to as "closed source".

4.2.1 Proprietary software licensing

A computer program is a sequence of instructions written by a human to be executed by computer. But computers can only execute instructions encoded as strings of binary numbers. So a computer program is first written in a form that can be read and understood by human beings, known as source code, and then translated by means of another program into binary form, known as machine or object code. To make useful modifications to a computer program, or to use parts of the program code in another program, it is necessary to have access to the source code. In addition to actual code, the source code document usually contains annotations intended to elucidate the design of the program, inserted by the programmer both as an explanation to others and as a personal reminder.[1]

Many biotechnology research tools are protected by patent, but source code historically has not been regarded as patentable subject matter because it is essentially a series of mathematical algorithms or mental steps and is therefore on the wrong side of the discovery-invention divide in patent law.[2] While patents protect inventions in the form of new products or processes, copyright protects the original expression of an idea; for this reason, source code has traditionally been protected as a literary work under copyright law. The owner of a copyrighted program has certain exclusive rights, including the right to reproduce and distribute the program and to prepare derivative works. Unlike patent protection, copyright protection applies to unpublished as well as published works, so source code can be simultaneously protected by copyright and as a trade secret.[3]

The upshot is that anyone who buys a copy of a typical proprietary software program is prevented from changing the program or using parts of the code to make a new program in two ways. First, the buyer – in fact a licensee – receives only the binary or machine code version of the program, the source code being kept secret. The licensor's employees who need access to the source code are required to sign nondisclosure agreements.[4] Second, even if the licensee did have

[1] von Krogh & von Hippel (2003).

[2] This position has been under siege since the 1981 case of *Diamond* v. *Diehr* (450 US 175), in which the United States Supreme Court ordered the Patent and Trademark Office (USPTO) to grant a patent on an invention using computer software to direct the process of curing rubber. Guidelines issued by the USPTO in 1995 and finalised in 1996 interpreted subsequent court cases as extending software patentability to programs that are essentially algorithms only distantly connected to physical processes: Computer-Related Inventions Examination Guidelines, 61 Fed. Reg. 7478 (Feb. 28, 1996). Software patents remain highly controversial.

[3] Software can also be protected under trademark legislation. Trademarks identify the source of goods, processes or services and may be used in conjunction with patent and/or copyright protection. Trademark protection is important in the open source software context: see chapter 7, section 7.2.2, p.212.

[4] As Bill Gates has explained, "a competitor who is free to review Microsoft's source code... will see the architecture, data structures, algorithms and other key aspects of the relevant Microsoft product[, making] it much easier to copy Microsoft's innovations": *State of New York* v *Microsoft Corporation*, Direct Testimony of Bill Gates, 18 April 2002, http://www.microsoft.com/presspass.trial/mswitness/002/billgates/billgates.asp at 307, 20 April 2002, cited in Fitzgerald & Bassett (2003), p.12.

access to the source code, he or she would be legally prevented from changing or building on it by the terms of the licence agreement: under a typical licence, the owner retains the exclusive right to redistribute or modify the program and authorises the making of only a limited number of copies. Most licences contain explicit restrictions on the number of users, the number of computers on which the program may be run and the making and simultaneous use of backups.[5] Typically a licensee may not reverse engineer the licensed product except as expressly authorised by applicable law: in Australia, a contract to override reverse engineering rights is prohibited by statute, while in the United States the law is less clear. A licensee may not rent, lease, lend or host products.[6] Thus, in current commercial practice most software is licensed for a fee rather than sold to a third party as intellectual property;[7] in other words, it is treated in essentially the same way as a manufactured good.[8] In return for the licensing fee, the user is offered a limited warranty that the product will perform substantially in accordance with user documentation for a period up to 90 days from first running the program. Whether the final product is sold by shrink wrap or click wrap licence, licensees are dependent on the vendor for upgrades and patches.[9]

4.2.2 Free software

In the early days of computer programming, these proprietary restrictions on access to and use of source code were rare. Instead, most users did their own programming and exchanged source code over the ARPANET, the precursor of the Internet, according to etiquette within a community made up largely of scientists and engineers employed in academic and corporate laboratories. But in the late 1970s to early 1980s, intellectual property aspects of commercialisation began to affect the culture of the computer science community in similar ways to those described in chapter 2 in relation to the molecular biology community of that time. Programmers left public sector institutions for better paid jobs with private companies, where they were asked to sign nondisclosure agreements as a condition of employment.[10]

One programmer who objected to these developments was Richard M. Stallman, a member of the Massachusetts Institute of Technology's Artificial Intelligence Laboratory, where the communal "hacker" culture of the 1960s and 1970s had been particularly strong. Stallman set out to create a suite of what he termed "free" software that would allow programmers to continue modifying and swapping software, including source code, without fear of being sued for breach of intellectual property rights.[11] The word "free" did not refer to price: rather, Stall-

[5] von Krogh & von Hippel (2003).
[6] Fitzgerald & Bassett (2003), pp.12-13.
[7] von Krogh & von Hippel (2003).
[8] Raymond (2001), chapter 5: "The Magic Cauldron". See below, section 6.2.1, p.144.
[9] Fitzgerald & Bassett (2003), pp.12-13.
[10] Levy (1984); Raymond (1999); DiBona et al. (1999); Stallman (1999).
[11] Stallman (1999).

man meant that software users should be at liberty to run a program for any purpose, to study how it works and adapt it to specific needs, to redistribute copies, and to improve the program and release those improvements.[12] To allow these freedoms, copyright owners would have to both provide physical access to the source code and remove legal restrictions from copyright licences.

In order to ensure that software developed as free software would continue to be available in all its derivative forms to the software development community at large, Stallman and his advisers devised a legal mechanism to enforce sharing in the form of an ingenious twist on the conventional copyright licence, known as "copyleft". The archetypal copyleft licence is the General Public Licence or "GPL", originally called the GNU Public Licence after the GNU project, Stallman's first step towards the creation of a complete suite of free software. (Begun in 1982, GNU – a recursive acronym that stands for "Gnu is not Unix" – involved the construction of an entire clone of the popular UNIX operating system.)[13] Under the terms of the GPL, the copyright owner grants the user the right to use the licensed program, to study its source code, to modify it, and to distribute modified or unmodified versions to others, all without having to pay a fee to the owner – with the proviso that if the user chooses to distribute any modified versions, he or she must do so under the same terms. The right to copy and redistribute under the GPL is subject to a requirement that the redistributed version carries a copyright notice and a disclaimer of warranties; the distributor may charge for the cost of distribution and may offer warranty protection for a fee. Derivative works distributed under the GPL must be identified as such, interactively if the program normally runs interactively. The work may be distributed in executable or binary form only, provided the source code is distributed with the executable or is made available for no more than the cost of distribution under a written offer valid for at least three years.[14]

More generally, copyleft licences are characterised by distribution terms that give licensees the rights to use, modify, and redistribute the program's code or any program derived from it on the condition that the same distribution terms apply.[15] Thus, copyleft is a way of guarding against the danger of technology "hijacking", a problem we have already encountered in the biotechnology context (see chapter 3).[16]

Although the simplest way to make a program free is to waive copyright and refrain from keeping trade secrets, thereby putting it into the public domain, this method allows follow-on innovators to distribute derivative works under restric-

[12]" 'Free software' is a matter of liberty, not price. To understand the concept, you should think of 'free' as in 'free speech', not as in 'free beer.'" Free Software Foundation web site, http://www.gnu.org/philosophy/free-sw.html

[13]Stallman (1999).

[14]Webbink (2003), pp.6-7.

[15]Free Software Foundation website, "What is Copyleft?", http://www.gnu.org/ copyleft/copyleft.html, last accessed 17 December 2004.

[16]In the software community a range of tactics are used to reinforce anti-hijacking licence terms: O'Mahony (2003).

tive licensing terms.[17] Using a copyleft licence instead means that even as the licensed software evolves into forms that might be sufficiently new to attract copyright protection in their own right, it remains freely available to users and developers. This is crucial to sustaining collaborative development over time because continuing access to the evolving program is an important quid pro quo for contributors, as illustrated by the comments of programmers who choose to copyleft their software:

> Because this is a very ambitious project I need help from the community. Consequently, I need to give some assurances to the community that my intentions are honourable and that I'm not going to turn out as some evil proprietary guy somewhere down the line and try to exploit the code that they contribute to me. ... [The GPL] creates fairness and honesty in the relationship between contributors on a project to ensure that if their contribution is born free it stays free as time goes on.[18]

Unsurprisingly, copyleft licence terms make software unattractive to some commercial users who may be concerned that mixing copylefted code with proprietary code could give rise to an obligation to reveal the source code of the proprietary component. This concern gives rise to the use of loaded terminology: copyleft licences are often described as "viral" or "infectious"; a piece of copylefted code might be referred to as a "tar-baby".[19] Lawrence Rosen, General Counsel to the Open Source Initiative, argues that the concern is exaggerated and suggests that copyleft provisions should be seen in a more positive light, as an "inheritance" rather than an "infection".[20] This issue is discussed in more detail below.

Although most free software is distributed under a copyleft licence, free software that is not copylefted also exists.[21] Software is considered "free" if it complies with the Free Software Definition promulgated by the Free Software Foundation (FSF), a non-profit organisation established by Stallman and others in 1985.[22] As the FSF website explains:

> Free software is a matter of the users' freedom to run, copy, distribute, study, change and improve the software. More precisely, it refers to four kinds of freedom, for the users of the software:
> The freedom to run the program, for any purpose (freedom 0).
> The freedom to study how the program works, and adapt it to your

[17]Free Software Foundation website, "What is Copyleft?", http://www.gnu.org/copyleft/copyleft.html, last accessed 17 December 2004.

[18]Gampe & Weatherley (2003), pp.120-121.

[19]Lita Nelsen, personal communication.

[20]Rosen et al. (2003), p.33.

[21]Free Software Foundation, "The Free Software Definition", http://www.gnu.org/philosophy/free-sw.html, last accessed 17 December 2004.

[22]According to its website, the Free Software Foundation accepts donations, but most of its income has always come from sales of copies of free software, and of other related services: http://www.gnu.org/gnu/thegnuproject.html, last accessed 17 December 2004.

> needs (freedom 1). Access to the source code is a precondition for this.
> The freedom to redistribute copies so you can help your neighbor (freedom 2).
> The freedom to improve the program, and release your improvements to the public, so that the whole community benefits (freedom 3). Access to the source code is a precondition for this.
> A program is free software if users have all of these freedoms.[23]

(Recall that according to Mertonian sociologists of science, the norm of communism encouraged scientists to communicate the results of their research to other scientists so as preserve scientific knowledge within the public domain, where it could be freely used and extended: see section 2.3, p.12.) The Free Software Definition is not a code: the FSF maintains a list of licences it considers "free", but emphasises that application of the Definition is a matter of interpretation and judgment to determine whether a particular licence fits the spirit as well as the letter of the stated criteria, which may evolve in response to licensing innovations.[24]

4.2.3 Open source software

The influence of the free software movement was initially limited because of industry suspicion of the notion of "free" software. In the late 1990s, Netscape hired programmer and essayist Eric S. Raymond to advise on an appropriate licence for a new internet browser; the experience of thinking about free software from a business perspective inspired Raymond and his fellow programmer, Bruce Perens, to look for an alternative terminology that would not be confusing or off-putting to those who did not share Stallman's view of proprietary software licensing as morally wrong.[25] In 1998 Raymond, Perens and others established the Open Source Initiative, a non-profit advocacy organisation that also acts as a certification body for open source licences.[26] Certification indicates compliance with an official Open Source Definition, based on guidelines originally developed by Perens and other users of the Debian GNU/Linux software distribution prior to publication of the Free Software Definition in order to help distinguish between licences that really did guarantee freedom to users and licences that had some similar features but were basically still proprietary licences.[27]

Thus, the term "open source" was coined essentially as a marketing strategy to promote the idea of free software to a commercial audience on pragmatic rather than ideological grounds (specific commercial applications of open source licences are discussed in chapter 7).[28] The Free Software Foundation and the

[23]Free Software Foundation, "The Free Software Definition", http://www.gnu.org/philosophy/free-sw.html, last accessed 17 December 2004.
[24]Ibid.
[25]Raymond (1999); Perens (1999); von Krogh & von Hippel (2003).
[26]Open Source Initiative, http://www.opensource.org/, last accessed 16 November 2004.
[27]Perens (1999).
[28]See especially section 7.2.2, p.209 and section 7.2.3, p.214.

Open Source Initiative maintain separate lists of approved licences,[29] but there are few practical differences between free and open source software: both seek to protect basically the same set of user rights – summed up as the freedom of "anyone, anywhere, for any purpose, to use, copy, modify or distribute either gratis or for a fee" any software licensed under a free or open source licence – and both identify disclosure of source code as a practical necessity for doing so.[30] Specifically, the imposition of reciprocal obligations on creators of derivative works is not the point of distinction between free and open source software: neither term necessarily implies that the software licence contains copyleft provisions. Nevertheless, the Free Software Foundation expresses a strong preference for the copyleft approach and is wary of mixing proprietary and non-proprietary licensing strategies, whereas proponents of open source regard this as acceptable and even desirable in order to capture greater "mindshare" within the developer community.[31] For reasons given at the start of chapter 7, in this thesis a conscious choice has been made to adopt the term "open source", with its connotation of trying to appeal to a business audience on the basis of economic self-interest, instead of referring to software (or biotechnology) "freedom".

4.3 Open source as a development methodology

In ordinary usage, the term "open source" has evolved two distinct meanings. First, open source refers to a specific and relatively well-defined approach to the licensing of intellectual property in software programs. Second, the term "open source" is also used to denote a less well-defined yet readily recognisable approach to software development, and an accompanying set of business strategies. Though distinct, these meanings are closely linked because (as noted earlier) the use of open source software licences plays a key role in motivating contributions to a collaborative development effort.[32] This section introduces open source development principles, which will be explored further in chapter 6; the next section deals with open source licensing, explored further in chapter 5.

4.3.1 A "typical" open source project?

Strictly speaking, the term "open source" refers to a software licence that is certified by the Open Source Initiative to conform with the official Open Source Definition. However, in ordinary usage "open source" also refers to the way soft-

[29]The Open Source Initiative's list is at http://www.opensource.org/licenses, last accessed 16 November 2004.

[30]Rosen et al. (2003), p.39.

[31]Open Source Initiative, 'Why "Free" Software is too Ambiguous': http://www.opensource.org/advocacy/free-notfree.php; Free Software Foundation, 'Why "Free Software" is better than "Open Source"': http://www.gnu.org/philosophy/free-software-for-freedom.html.

[32]This is true even of non-copyleft licences: though they do not preserve ongoing access to an evolving technology, such licences do provide a minimum level of protection for the integrity of an author's code: see above, note 29.

ware has been developed. Although the development methodology aspect of open source is far less clearly defined than the licensing aspect, some characteristic practices of open source development have been identified that distinguish it from ordinary commercial software development.[33]

The project often regarded as the archetypal open source software development effort grew out of the GNU project, mentioned in the previous section. GNU development was co-operative, in that it drew on contributions of code and effort from many individuals as well as donations of machines and money from computer manufacturers. By 1990, Stallman's Free Software Foundation had developed almost all the components of a UNIX-like operating system, except for the kernel. (The kernel is the core of a computer operating system; it provides basic services for all other parts of the operating system, including those that respond to user commands.) In 1991, a Helsinki University student named Linus Torvalds began developing a free UNIX kernel using tools made available by the Free Software Foundation. He made good progress, and his initial success attracted many helpers: the kernel, known as Linux, quickly became a full featured UNIX with entirely free and redistributable source code. By late 1993, GNU-Linux could compete on stability and reliability with many commercial UNIXs and hosted vastly more software.[34]

Before Linux, most people in the software development community, including the free software movement, believed that any software as complex as an operating system had to be developed in a carefully coordinated way by a relatively small, tightly knit group of people. But Linux evolved completely differently. Almost from the start, it was worked on rather casually by huge numbers of volunteers co-ordinating only through the Internet, which was just starting to take off around the early 1990s. Quality was maintained not by rigid standards or micromanagement, but by the simple strategy of releasing the code every week and getting almost instantaneous feedback from hundreds of users – a sort of rapid Darwinian selection on the mutations introduced by developers. In a famous essay, Eric S. Raymond likened these two styles of development to a cathedral, built to a single architectural vision, and a bazaar, an emergent phenomenon with no discernible leadership.[35] Though not in fact wholly accurate, in that Torvalds did exert considerable control over the development of Linux, this simile has entered into open source lore because it highlights the difference between a centrally planned approach to software development and the more decentralised approach described below.

Although Linux is often regarded as a "typical" open source software development project, in fact it is only one of some twelve thousand open source projects currently underway, involving an estimated 120,000 developers – numbers that are reported to be increasing steadily.[36] The number of developers in each project ranges from a mere handful to many thousands. Similarly, the num-

[33]von Krogh & von Hippel (2003); Bonaccorsi & Rossi (2003).
[34]Raymond (1999).
[35]Raymond (2001), chapter 3: "The Cathedral and the Bazaar".
[36]Bonaccorsi & Rossi (2003).

ber of users of each program produced by open source methods ranges from a few to many millions. Programs at the larger end of the scale in terms of user numbers include Apache server software, the Perl programming language and the GNU-Linux operating system itself; other well known open source programs include BIND and the email program Sendmail, both "killer" applications in their respective market niches.[37]

Thus, while Linux is certainly a prominent example of an open source software development project, its characteristics are not actually representative of the majority of such projects. What, then, is a "typical" open source project? Despite wide variations in the size of the developer group, in user numbers and in the type of application being developed, most open source projects do have certain features in common in addition to the distribution of code under an open source licence. While not definitive, these features constitute a recognisable "family resemblance".[38] A typical project is initiated by an individual or a small group who are prospective users of the finished program; the intended use is usually (not always) connected with the initial developers' professional activities, which may be carried out in either an academic or commercial setting. This group develops a rough version of the program, perhaps with only basic functionality – enough to act as a "seed" for further development. This version is made freely available for download over the Internet, often through a clearinghouse site such as SourceForge.net,[39] under a specified open source licence; the initial developers may also establish discussion and mailing lists for the project. If the basic version succeeds in attracting interest, some users will create new code and may post that code on the project website for others to use and generate feedback. This second tier of developers may be independent voluteers, but are often employees of firms that support the project, and though some may be motivated by a desire to enhance personal self-esteem or develop a reputation for skilful programming, many have a more direct economic interest in participating.[40] New code that is of sufficient quality is then added to an authorised or official version of the program on the say-so of the project maintainers, a core group that is almost always the same as or a subset of the initial developer group – at least at first: the project leadership may change over time as participants' needs and priorities evolve.[41]

4.3.2 Principles of open source software development

Raymond's essay "The Cathedral and the Bazaar" identified several features of open source software development that he considers important to its success.[42] First, Raymond says that "good programmers know what to write; great ones

[37] von Krogh & von Hippel (2003).

[38] Bonaccorsi & Rossi (2003); von Krogh & von Hippel (2003).

[39] See http://sourceforge.net/.

[40] Possible motivations to contribute to an open source project are discussed in more detail in chapter 6, section 6.3 and chapter 7, section 7.2.2.

[41] Bonaccorsi & Rossi (2003); von Krogh & von Hippel (2003).

[42] Raymond (2001).

know what to rewrite and reuse" – in other words, successful programming is an incremental process of innovation, requiring access to previously developed code. Second, the best programs are written in response to a user-developer's own perceived need, which Raymond refers to as "scratching a personal itch". Third, "given enough eyeballs, all bugs are shallow": treating users as codevelopers allows bugs to be identified and removed more quickly and effectively. Fourth, programs are best released "early and often" to encourage feedback from users.

It is easy to see strong parallels between these principles and the ideas we encountered in chapter 2, from sociology of science literature about the relative merits of centralised and decentralised scientific research to economics and intellectual property literature dealing with whether certain economic justifications for patent rights (in particular, Kitch's "prospect development model") are suited to the needs of basic scientific research. Whether by convergent (adapting to the same pressures) or divergent (derived from the same ancestors) evolutionary processes, or both, the open source development model shares many of its claimed advantages with traditional academic scientific research, both in computer science and in biotechnology:

> When programmers can read, redistribute, and modify the source code for a piece of software, the software evolves. People improve it, people adapt it, people fix bugs, and this can happen at a speed that, when one is used to the slow pace of conventional software, seems astonishing. The open source community has learned that this rapid evolutionary process produces better software than the traditional closed source model, in which only a few programmers can see the source and where everybody else must blindly use an opaque block of bits.[43]

In his article "Coase's Penguin, or, Linux and The Nature of the Firm", Yochai Benkler argues that both open source software development and traditional scientific research are examples of "commons-based peer production", a means of ordering productive activity that is often overlooked in favour of managerial and market-based systems.[44] While acknowledging that peer production is nothing new, Benkler argues that computer networks are bringing about a change in the scope, scale and efficacy of peer production such that it can be applied to larger and more complex tasks. He identifies three components in the chain of information production – generation of content, accreditation and determination of relevance, and distribution – and gives examples of how each component is being produced on the Internet using a peer based model with respect to information and cultural goods other than software.[45] From these examples Benkler attempts

[43]Open Source Initiative website, http://www.opensource.org.

[44]Benkler (2002).

[45]With respect to content, Benkler cites NASA Clickworkers, Wikipedia, Kuro5hin and multiplayer and online computer games like Ultima and Everquest; with respect to relevance and

to abstract some general principles about peer production, what makes it work, and what makes it better under certain circumstances than methods of ordering production that rely on either market signals or managerial direction. We return to Benkler's observations in later chapters.

4.3.3 Open source development as a business strategy

In fact, the features of the open source development model that are emphasised by its proponents – speed, efficiency, quality, responsiveness to user need – are exactly the features of the innovative process that, as we saw in chapter 3, are apparently being lost in the biotechnology context through commercialisation and the accompanying proliferation of intellectual property rights. Yet the open source community has managed to retain these features without necessarily rejecting either commercialisation or certain kinds of intellectual property rights in software.[46] As the Free Software Foundation website points out:

> "Free software" does not mean "non-commercial". A free program must be available for commercial use, commercial development, and commercial distribution. Commercial development of free software is no longer unusual; such free commercial software is very important.[47]

Indeed, recent research suggests overall revenue for servers, desktops, and packaged software running on GNU/Linux will reach $US35.7 billion in the next four years.[48]

Why might the open source model of software development appeal to commercial users and developers? From a user or customer perspective, the most often cited factors are quality, better security and reliability, and freedom from dependence on a single software vendor.[49] Users who are also developers also have the opportunity to influence the direction of development to better match their own commercial needs. From a developer perspective, the principal advantage to opening up the development process to enable contributions from outside the company is that it provides access to more creativity at a lower cost and with shorter development times: as businessman Yancy Lind has commented, the "giants of this industry... have hundreds of engineers working on these products.

---

accreditation he cites Amazon, Google, the Open Directory project and Slashdot; and for distribution he cites Napster and Project Gutenberg.

[46] As discussed earlier, the free and open source software community has embraced copyright in software to the extent of using the copyleft mechanism to guarantee ongoing access to evolving technology; on the other hand, the community has little use for software patents.

[47] Free Software Foundation, "The Free Software Definition", http://www.gnu.org/philosophy/free-sw.html, last accessed 17 December 2004.

[48] Keizer (2004).

[49] In a ten month test for reliability run by ZDNet, NT servers crashed an average of once every six weeks, the GNU/Linux servers never went down – Fitzgerald & Bassett (2003), p.19, citing David A. Wheeler, "Why Open Source Software/Free Software? Look at the numbers!", http://www.dwheeler.com/oss_fs_why.html 23 April 2002.

I have forty. ... [O]pen source is something I can leverage... to give me a real economic advantage".[50]

Other related advantages include encouraging adoption of the developer's technology as an industry standard, thereby obtaining a competitive advantage in complementary markets; encouraging other developers to produce applications on your platforms (sometimes referred to as "capturing developer mindshare"); building goodwill; and gaining access to government procurement contracts where the tender process stipulates a preference for open technologies.[51] In Australia, federal legislation requiring consideration of open source software in decision-making concerning public agency procurement contracts has been proposed in order to address concerns that "a small number of software manufacturers have a disproportionate and restrictive hold on the supply, use and development of software",[52] concerns essentially the same as those described in chapter 3 in relation to corporate tenure over data streams in biotechnology research and development.

Clearly, the range of commercial possibilities associated with any particular software program is affected by the developer's choice of licence, especially the choice between copyleft and non-copyleft licences (see section 5.4.4, p.129, and section 7.2.3, p.214). More generally, in relation to the commercial applications of open source software development, it is important to be aware that although open source is generally regarded as a proven development methodology within the software industry, many still question its long term significance and prospects of success in the marketplace.[53] These issues are discussed further in chapter 7 (section 7.3, p.218). For the present it is sufficient to note that the "proof of concept" for open source biotechnology is not tied to the ultimate success or even survival of open source software. The proof of concept for biotechnology is in biotechnology: open source software is not a rigid formula for success, but the basis for an analogy – though it is a powerful analogy.

4.4 Open source as a licensing scheme

We saw in the previous section that the key features of open source licensing are the same as those of free software licensing (indeed, many licences, including the GPL, are on the approved lists of both the Free Software Foundation and the Open Source Initiative). Both types of licence ensure "the right of anyone, anywhere, for any reason, to copy, modify and (for free or for money) distribute the

[50] Yancy Lind, quoted in Rosen et al. (2003), p.53.

[51] In the US, a recent study conducted on behalf of the Department of Defense concluded that open source had the potential for large direct and indirect cost savings for military systems requiring large deployments of costly software products; similar considerations have driven governments in Taiwan, Germany, China and Peru to adopt open source software for government use.Fitzgerald & Bassett (2003), p.16.

[52] Bassett & Suzor (2003), p.13.

[53] Rosen et al. (2003), p.54.

software, and to have the source code that makes those other things possible".[54] However, the Open Source Definition (OSD) is somewhat more detailed than the Free Software Definition. In this section we look more closely at each of its criteria; this dicussion will serve as a point of departure for an analysis (in chapter 5) of the feasibility of implementing open source licensing principles in the context of biotechnology research and development.

4.4.1 Elements of the Open Source Definition

1. Free redistribution

The first criterion in the OSD is that an open source licence must "not restrict any party from selling or giving away the software as a component of an aggregate software distribution containing programs from several different sources. The license shall not require a royalty or other fee for such sale."[55] This means a user can make any number of copies of the software, and sell or give them away, without having to pay for that privilege.[56] The Open Source Initiative website annotation of the OSD explains the rationale for this criterion: "[b]y constraining the license to require free redistribution, we eliminate the temptation to throw away many long-term gains in order to make a few short-term sales dollars. If we didn't do this, there would be lots of pressure for co-operators to defect."[57]

"The license shall not restrict any party from selling or giving away the software"/"The licence shall not require a royalty or other fee for such sale" An OSD-compliant licence need not prevent the licensor from charging a fee for access to his or her technology.[58] However, such a licence cannot allow the licensor to control the licensee's subsequent use of the technology either by prohibiting the exercise of any of the standard copyright rights (copy, modify, distribute) or by making the exercise of those rights conditional on the payment of a royalty or other fee to the licensor. In other words, under an OSD-compliant licence, once a user has been granted access to the technology (whether for free or for a price), he or she can exercise all the rights that would otherwise be exclusive to the owner without incurring any further obligations. As Lawrence Rosen puts it, "whatever they charge for, you only have to buy once".[59]

Although there is nothing in the OSD that prevents the charging of one-off fees, in practice the free (unrestricted) redistribution requirement means market pressure will tend to force the price of access to the technology down to the lowest

[54]Lawrence Rosen, personal communication.

[55]This and all other references to the OSD in the remainder of this thesis are to The Open Source Definition (Version 1.9), available at http://www.opensource.org/docs/definition.php, last accessed 21 December 2004.

[56]See Perens (1999).

[57]The Open Source Definition (version 1.9).

[58]Rosen et al. (2003), p.40.

[59]Lawrence Rosen, personal communication.

fee that any of the distributors chooses to charge – which is often zero. Some distributors may be able to charge a higher price based on the value of their brand, but even in such a case the market will not bear as high a price as if every licensee had not been a potential distributor (because the price charged by any distributor can be undercut, even to the point of giving the software away gratis, by any other licensee) .

As Rosen points out, the fact that the price of software itself tends toward zero under free and open source software licences does not exclude other ways of making money from software.[60] As noted earlier, we will return to this issue in chapter 5, but one phenomenon not discussed elsewhere is worth noting: that of dual licensing. Technology obtained under an open source licence must be distributed under an open source licence (see criterion 7 of the OSD, below), and an ordinary licensee normally has no legal right to distribute it in any other way. But the developer of new technology can licence the same technology under both proprietary and open source licences. For example, the GPL requires a licensee to licence derivative works under the GPL, but doesn't prevent him or her from also licensing the same technology under a proprietary licence which permits charging a conventional licence fee, perhaps to a commercial entity that does not want to have to conform to the GPL in its turn. Charging for code that is available for free is a surprisingly common way for open source developers to make money.[61]

"Shall not restrict" Some types of restrictions on redistribution are in fact permissible in free and open source licences. For example, copyleft is itself a restriction on redistribution, also known as a reach-through provision. However, this restriction is considered acceptable because it protects rather than conflicts with the central freedoms of free and open source software.[62] Similarly, rules about how to package a modified version are acceptable if they do not effectively block users' freedom to release modified versions, as are some rules to the effect that if a program is released in one form it must be released in another form also in order to enhance accessibility; it is also acceptable for a licence to require that a user who has distributed a modified version must provide a copy of that version to any previous developer on request.[63]

"Selling or giving away" Lawrence Rosen has commented that this phrase is badly worded, and has recommended that it be amended to read, "the licence must permit anyone to distribute copies or derivative works free or for a price"

[60] Rosen et al. (2003), p.39.

[61] Bill Lard, in Rosen et al. (2003), p.61. Note, however, that dual licences become difficult to administer in relation to software programs that have been developed by more than one programmer because redistributing under multiple licences requires the co-operation of all the authors: see http://openacs.org/about/licensing/open-source-licensing, last accessed 16 November 2004.

[62] Free Software Foundation, "The Free Software Definition" http://www.gnu.org/philosophy/free-sw.html.

[63] Ibid.

(or something to the same effect).[64] Presumably the new wording would eliminate any confusion between distributing copies of software and alienating intellectual property rights to the software itself.

"As a component of an aggregate software distribution" This phrase is an historical artefact originally intended to plug a loophole in the Artistic Licence, a licence originally designed for the programming language Perl (very commonly used in bioinformatics software). Most programs that use this licence are now also available under the GPL, so this phrase is no longer needed and may disappear from future versions of the OSD.[65] The essential meaning of this criterion would be unaltered if this phrase were simply replaced by the words "the software".[66]

2. Source code

The second criterion in the Open Source Definition is that an open source licence must require that users be given access to the source code for a licensed program, and "must allow distribution in source code as well as compiled form. Where some form of a product is not distributed with source code, there must be a well-publicised means of obtaining the source code for no more than a reasonable reproduction cost – preferably, downloading via the Internet without charge. The source code must be the preferred form in which a programmer would modify the program. Deliberately obfuscated source code is not allowed. Intermediate forms such as the output of a preprocessor or translator are not allowed."[67] The following rationale is given on the Open Source Initiative website: "We require access to un-obfuscated source code because you can't evolve programs without modifying them. Since our purpose is to make evolution easy, we require that modification be made easy."[68]

"Source code" As we saw earlier, source code is a necessary preliminary for the modification of a program.[69] In an effort to counter the public relations effects of the open source movement, some proprietary software companies have begun providing access to source code. However, in the open source context, access to source code is not an end in itself, but a necessary precondition to the exercise of other user rights.[70]

"The program must include source code. Where some form of a product is not distributed with source code, there must be a means of obtaining the source

[64] Lawrence Rosen, personal communication.
[65] Perens (1999).
[66] Lawrence Rosen, personal communication.
[67] The Open Source Definition (Version 1.9).
[68] Ibid.
[69] Perens (1999).
[70] Lawrence Rosen, personal communication.

code" Note that open source licences do not require a user who simply copies or modifies the licensed software for his or her own use to make the source code publicly available. This obligation arises only if the licensee chooses to distribute – not simply develop and use – a copy or modified version of the original program:

> [T]he best example I've heard is the US military using open source software to do some of the targeting control on some of their gunships. There was this big issue of well, do they need to release the source code? The answer... is no, because they are not making available their program to the public. That is their program. They took the source and they are using it for their own purposes.[71]

Licences that require too much of users in this respect have been rejected by the Open Source Initiative. For example, a well-known company proposed a licence for some of its software that required anyone who made improvements to the code to disclose those improvements to the company. This requirement was considered unacceptable because it was not restricted to software distributions, but also applied to modifications intended for in-house use; even though in-house use might involve issuing the modified program to hundreds of thousands of employees, it is not a "distribution" of the software.[72]

The requirement to provide source code can be met in various ways under different licences. For example, the GPL requires that if the source code is not distributed with the executable program, it must be made available to anyone who requests it for three more years. One way to meet this requirement is to keep the information on the Internet where it can be indexed by search engines: "this way, people can access the information without bothering you".[73] Interestingly, some open source licences do not in fact meet the requirement of obliging on-licensing users to make the source code publicly available (one example is the Berkeley Software Distribution or "BSD" licence, which does not include a clear definition of source code). The explanation is that the OSD came into existence after certain licences were already in use and those licences were "grandfathered in" to the approved list.[74]

"Preferred form in which a programmer would modify the program" Given the obligation to provide source code in the preferred form in which a program-

[71] Drew Endy, personal communication.

[72] Lawrence Rosen, personal communication.

[73] Bruce Perens, personal communication. For example, clause 3 of Version 1.0 of the Open Software Licence reads: "Licensor hereby agrees to provide a machine-readable copy of the Source Code of the Original Work along with each copy of the Original Work that Licensor distributes. Licensor reserves the right to satisfy this obligation by placing a machine-readable copy of the Source Code in an information repository reasonably calculated to permit inexpensive and convenient access by You for as long as Licensor continues to distribute the Original Work, and by publishing the address of that information repository in a notice immediately following the copyright notice that applies to the Original Work."

[74] Lawrence Rosen, personal communication.

mer would modify the program, the question arises how to determine what is the preferred form. One of the clearest definitions of source code in an open source licence is in clause 3 of the Open Software Licence: "'Source Code' means the preferred form of the Original Work for making modifications to it and all available documentation describing how to access and modify the Original Work."[75] However, as the author of this licence explains:

> I'm not talking about documentation in general. People must have the right to sell proprietary documentation for open source software. That doesn't mean the documentation itself becomes open source. If I write a book that tells people how to do Linux, I can do that and sell it and I don't have to release that book under an open source licence. But if it is documentation on how to modify the work, that they have to provide. So if it is documentation explaining how to change the program and create a derivative work, if I write such documentation for my software that says, "If you want to do that here's how to change the source code", then that's relevant documentation. Not putting that out is like obscuring the source code.[76]

"Deliberately obfuscated source code is not allowed" As the stipulation that source code must be in its "preferred form" implies, it is possible to obfuscate source code. In fact, there exists at least one program that takes source code and removes all the spaces and new lines so that the reader is left with a block of code that is almost indecipherable.[77] Obfuscation is hard to prove, but anecdotal evidence suggests that users generally comply with this term; if a dispute reached the point of litigation, presumably it would be possible in the discovery process for a litigant to ask to see the software owner's employees using the code in the form in which it has been made publicly available.[78]

3. Derived works

The third criterion in the Open Source Definition is that an open source licence must "allow modifications and derived works, and must allow them to be distributed under the same terms as the license of the original software."[79] The explanation for this criterion is that "the mere ability to read source isn't enough to support independent peer review and rapid evolutionary selection. For rapid evolution to happen, people need to be able to experiment with and redistribute modifications."[80] Note that in order to comply with the OSD a licence must allow, but need not *require*, modified works to be distributed under the same terms

[75] Version 1.0, dated 9/25/2002.
[76] Lawrence Rosen, personal communication.
[77] Bruce Perens, personal communication.
[78] Bruce Perens, personal communication.
[79] The Open Source Definition (Version 1.9).
[80] Ibid.

as the original software. As mentioned earlier, open source licences vary in this respect: the GPL does contain a copyleft provision, while the BSD licence does not.

The open source community has experienced some problems with the concept of derivative works in open source licences, attributed by community leaders to two factors. The first is that the definition of derivative works in copyright law is unsatisfactory in relation to software. Discussion of this point with community leaders highlighted an interesting corollary of the use of copyleft licences to preserve ongoing access to evolving software code: because copyleft is technically an exercise of a copyright owner's exclusive rights, a victory in the proprietary campaign for stronger copyright may actually reinforce copyleft freedoms (depending on what actions are taken to constitute infringement). While this means the copyleft mechanism is very robust, it can also create some tension for proponents of free and open source software. For example, *Galoob* v. *Nintendo* was a well known 1992 case in the United States Ninth Circuit Court of Appeals which established the rights of users to modify copyrighted works for their own use.[81] Galoob manufactured a product which allowed users to modify video games, including games sold by Nintendo, so as to make the user's character invincible. Nintendo sued Galoob, arguing that its product created derivative works that infringed Nintendo's copyright in its games. The Court held that Galoob's product did not create a derivative work because it did not directly modify the Nintendo software, but worked by modifying a data location in the game. The sentiment expressed by the district court – that "having paid Nintendo a fair return, the consumer may experiment with the product and create new variations of play, for personal enjoyment, without creating a derivative work" – is broadly consistent with the open source position. However, in practice the Nintendo case has sometimes been invoked in order to legitimate the sidestepping of obligations relating to derivative works under the GPL.[82]

The second factor that causes uncertainty with respect to derivative works is that not all open source licences incorporate established legal terminology. Lawrence Rosen has described the GPL as "extremely vague about what you are really entitled to do", noting that among users of open source software expressions such as "derivative work", "work based on the work" and "combined works" convey different meanings to different people even though they are commonly assumed to refer to clear and distinct categories:

> [I]n my licences I say, "You have the right to create a derivative work". What is a derivative work? Well, go to the court, look at the cases. You can talk about static and dynamic linkage – but a court is not going to deal with that, just because you in your public writings have defined those extra terms. No, the court is going to look at the four corners of the contract and say, "What the hell did you intend?"[83]

[81] *Louis Galoob Toys, Inc.* v. *Nintendo of America, Inc.*, 964 F.2d (9th Cir. 1992).
[82] Bruce Perens, personal communication.
[83] Lawrence Rosen, personal communication.

Even apart from uncertainty over the definition of a "derivative work", some software authors are wary of the open source requirement to allow modifications and derivative works to be distributed under the same terms as the original software, either because they are concerned about the integrity of the work and the effect of modifications on their reputations as programmers, or because they are concerned about modifications being made to serve criminal purposes. The first of these concerns is essentially a question of moral rights and is at least partially dealt with in the fourth paragraph of the OSD (see below). The second is based on a common misunderstanding about the function of a licence agreement: no licence has any valid existence outside an existing legal framework, and the use of software to commit crimes is covered by applicable criminal law without any need for a specific provision in the licence itself.[84]

4. Integrity of the author's source code

The fourth criterion in the Open Source Definition is that an open source licence "may restrict source code from being distributed in modified form only if the license allows the distribution of 'patch files' with the source code for the purpose of modifying the program at build time. The license must explicitly permit distribution of software built from modified source code. The license may require derived works to carry a different name or version number from the original software."

The rationale for this requirement is to permit a software author to enforce a separation between his or her own work and modifications that, if perceived to be part of that work, might reflect poorly on the original author.[85] Thus, though an open source licence must guarantee the availability of source code, it may require that the source code be distributed as unmodified base sources plus patches so that modifications can be readily identified.[86] Programs that automatically merge patches into the main source can be run when extracting a source package, so such a requirement need not make any practical difference to users, although some may consider it inelegant; popular Linux distributions like Debian and Red Hat use this procedure for modifications to their versions of Linux.[87]

5. No discrimination against persons or groups

The fifth criterion in the Open Source Definition is that an open source licence must not discriminate against any person or group of persons.[88] The reasoning behind this requirement is the same as that described in chapters 2 and 3: that "in order to get the maximum benefit from the process, the maximum diversity of persons and groups should be equally eligible to contribute to open sources."[89]

[84]Perens (1999).
[85]Perens (1999).
[86]The Open Source Definition (Version 1.9).
[87]Perens (1999).
[88]The Open Source Definition (Version 1.9).
[89]Ibid.

Export restrictions In explaining this requirement, the Open Source Initiative website notes that some countries, including the United States, have export restrictions for certain types of software. An OSD-compliant license may warn licensees of applicable restrictions and remind them that they are obliged to obey the law, but it may not incorporate such restrictions itself.[90] This requirement avoids imposing extra constraints on activities and people outside the relevant jurisdiction through the terms of the licence itself.[91]

Other restrictions on distribution of software to persons or groups Apart from government export restrictions, some software licences attempt to forbid distribution to people or groups outside jurisdictions with a certain standard of intellectual property protection. Such licences do not comply with the OSD, even if the reason for the restriction is to ensure that copyleft provisions can be enforced. One example of a licence that fails to comply with this aspect of the OSD even though it is in many other respects an open source licence is the Sun Community Licence.[92]

Examples of other restrictions that are prohibited under the OSD include restrictions based on political criteria. For example, a licence provided by the University of California during the time of apartheid in South Africa prohibited an electronic design program from being used by South African police. This prohibition made little sense after apartheid broke down, but users whose software was acquired under that licence must still apply this restriction to distributions of derivative works.[93]

6. No discrimination against fields of endeavour

The sixth criterion in the Open Source Definition is that an open source licence "must not restrict anyone from making use of the program in a specific field of endeavor. For example, it may not restrict the program from being used in a business, or from being used for genetic research."[94] As with the prohibition on territorial and other restrictions discussed in the previous section, the motivation behind this criterion is that maximum diversity of participants in software development is desirable; even though participation may be regulated in other ways, the authors of the OSD took the view that it should not be controlled by open source licences themselves. Bruce Perens, primary author, gives two specific reasons. The first is that open source licences should be useful for commercial purposes because there is "little incentive for anyone to develop software for academic use only".[95] The second reason to avoid restrictions on field of use was to

[90]Ibid.

[91]Free Software Foundation, "The Free Software Definition", http://www.gnu.org/philosophy/free-sw.html; Lawrence Rosen, personal communication.

[92]Bonaccorsi & Rossi (2003), p.1249.

[93]Perens (1999); Bruce Perens, personal communication.

[94]The Open Source Definition (Version 1.9).

[95]According to the Open Source Initiative website, "[t]he major intention of this clause is to prohibit license traps that prevent open source from being used commercially. We want commer-

forestall controversy within the developer community over politically sensitive applications of open source software:

> I foresaw that type of thing just getting in the way... . I just did not want to see, for example, pro-choice software and pro-life software... . I decided allowing everything was less complicated and would be of more benefit overall.[96]

7. Distribution of licence

The seventh criterion in the Open Source Definition is that under an open source licence, "rights attached to the program must apply to all to whom the program is redistributed without the need for execution of an additional license by those parties."[97]

This requirement raises the question whether open source software licences are technically contracts or merely copyright permissions: the latter can be unilateral, but formation of a contract requires acceptance on the part of the licensee and it is therefore doubtful whether automatic, no-signature-required licences can incorporate contractual obligations (such as an obligation to provide source code when distributing derived works). This issue – which is closely linked with the questions of how to achieve a proper manifestation of assent in relation to a contractual licence and the degree to which the method used can be dictated by an open source licence, dealt with below in connection with paragraph 10 of the OSD – is the subject of considerable controversy within the free and open source software community and has not yet been the subject of an authoritative pronouncement by the courts. The arguments on both sides are essentially pragmatic.

The disadvantage from the open source perspective of a contractual approach is that a contract allows the imposition of a wider range of restrictions on the use of the technology, which means "there are many possible ways such a licence could be unacceptably restrictive and non-free".[98] In addition, contract terms are arguably more costly to enforce because of variations in contract law from one jurisdiction to another; if the licence is characterised as a copyright permission, it is subject to copyright law – harmonised under the Berne Convention and, in the United States, codified in a federal statute. On the other hand, it is argued, the inclusion of quintessentially contractual provisions such as a disclaimer of warranty and the requirement to publish source code does not sit easily with the argument that the GPL is a mere copyright permission. Further, characterising

---

cial users to join our community, not feel excluded from it."; The Open Source Definition (Version 1.9).

[96]Bruce Perens, personal communication. Elsewhere, Perens has commented that although he believes political arguments belong on the floor of Congress, not in software licences, this view is itself controversial: Perens (1999).

[97]The Open Source Definition (Version 1.9).

[98]Free Software Foundation, "The Free Software Definition", http://www.gnu.org/philosophy/free-sw.html: The Free Software Definition.

the licence as a contract would mean that any licensee – not just the author or his or her assignee – would have standing to enforce its terms.[99] Rosen describes the Open Software Licence as the GPL rewritten as a contract: "I took the concepts of the GPL and what it intended to accomplish, and rewrote it as a contract and then I added the provisions that copyright law could not deal with. ... [This way] I have the advantage of being able to save that contract no matter what the governing law is [by adding] provisions that say the licensor's jurisdiction sets the venue and jurisdiction – he or she is giving you the software, if you do something illegal with it you have to deal with that in his or her courts."[100] The debate over whether the GPL is a contract or a licence permission is not, however, of sufficient relevance in the biotechnology context to be discussed in any detail here. For a discussion of issues relating to translating copyleft principles into biotechnology licensing, see section 5.4.4, p.130.

8. Licence must not be specific to a product

The eighth criterion in the Open Source Definition is that the rights attached to licensed software "must not depend on the program's being part of a particular software distribution. If the program is extracted from that distribution and used or distributed within the terms of the program's license, all parties to whom the program is redistributed should have the same rights as those that are granted in conjunction with the original software distribution."[101]

This criterion is intended to prevent licensors from tying open source-style freedoms to a particular product, for example by specifying that a product that is identified as open source is only free if it is used with a particular brand of Linux distribution: the product must remain free even if it is separated from the rest of the software "package" it came in.[102]

9. Licence must not restrict other software

The ninth criterion in the Open Source Definition is that an open source licence "must not place restrictions on other software that is distributed along with the licensed software. For example, the license must not insist that all other programs distributed on the same medium must be open-source software."[103] The Open Source Initiative website annotation explains that distributors of open source software have the right to make their own choices about their own software, and points out that the GPL complies with this requirement because software only inherits (or is "infected" with) the GPL if the two programs form a single work, not if they are merely distributed together.[104]

[99]Lawrence Rosen, personal communication.
[100]Lawrence Rosen, personal communication.
[101]The Open Source Definition (Version 1.9).
[102]Perens (1999).
[103]The Open Source Definition (Version 1.9).
[104]Ibid. This is the distinction between aggregation (two programs being included on the same CD-ROM) and derivation (one program incorporates part of another program into itself): Perens

10. Licence must be technology neutral

The tenth and final criterion in the Open Source Definition is that "no provision of [an open source] licence may be predicated on any individual technology or style of interface.[105]

As discussed earlier, at least some open source licences operate as contracts and therefore cannot come into existence without a "meeting of the minds" between licensor and licensee. Case law indicates, though not conclusively, that in the case of software that is physically distributed (for example on a boxed CD-ROM), a licensee accepts the relevant licence conditions by opening the program's shrink-wrap, even if the licence is not readable before the wrapping is removed.[106] However, in the case of digitally distributed software, mere downloading is not sufficient, and case law suggests that the licensee must "plainly manifest consent" in a click-wrap agreement.[107]

As the Open Source Initiative website points out, licence provisions mandating "click-wrap" assent may conflict with important methods of software distribution such as FTP download, CD-ROM anthologies, and web mirroring; such provisions may also hinder code re-use. Redistribution of the software may take place over non-Web channels that do not support click-wrapping of the download; similarly, licensed code (or re-used portions of such code) may run in a non-GUI environment that cannot support popup dialogues.[108] Therefore, other ways for the licensee to manifest assent must be allowed under open source licences. Lawrence Rosen elaborates:

> If there is a contract, there must be a mechanism for the manifestation of assent. But you cannot, within the constraints of the Open Source Defintion, impose technical constraints on the creators of derivative works; you must leave them free to do whatever they want. ... If I require clickwrap and then reimplement or create a derivative work where there is nothing to click, the licence doesn't apply, so you are limiting the evolution of the software. So what I say in the licence is that it must contain a manifestation of assent, and let them figure out how to do it.[109]

(1999).

[105]The Open Source Definition (Version 1.9).

[106]Judge John Vittone, Chair, American Bar Association Working Group Report on the Uniform Computer Information Transactions Act (UCITA) http://www.abanet.org/ucita/report_on_ucita.pdf, January 31, 2002. Note that the enforceability of such a licence may depend on the fairness of the provision sought to be enforced.

[107]Fitzgerald & Bassett (2003), p.33.

[108]The Open Source Definition (Version 1.9).

[109]Lawrence Rosen, personal communication. Note that in practice, some open source software can be accessed without the user having to accept the terms of the relevant licence in a formal click-through process: James (2003), pp83-84. In fact, under clause 5 of the GPL, the licensee is taken to have assented to the licence conditions whenever he or she modifies or distributes the licensed program or any work based on the program, ostensibly removing the need for any other manifestation of assent. (Although courts might not regard this as sufficiently unambiguous to

4.4.2 Specific open source licences

A spectrum of freedoms

Existing open source software licences lie at different points along a spectrum characterised by the amount of freedom given to licensees, and conversely the amount of freedom the copyright owner retains with respect to how he or she can make money from the software (discussed further in chapter 7). Any software author who wants to follow an open source licensing strategy must strike an appropriate balance between these two priorities. It is self-evident that software authors and their employers will value their own freedom to sell or lease their products in any way they choose. But freedom for users is also a priority for the software owner because use of an open source licence to encourage collaborative development relies on providing sufficient user access to the code, and sufficient freedom in the way it may be used, to facilitate and motivate contributions to its improvement.

There is a norm within the open source software community against proliferation of licences, so although it is always possible to write an entirely new licence that is perfectly tailored to a software owner's purposes, it is expected that licensors will model their chosen licence as closely as possible upon an existing licence that has been accepted within the community and is demonstrably workable.[110] It is therefore necessary when considering an open source strategy to decide what is important in a licence and identify which of the key existing licences comes closest to striking the appropriate balance between freedom for users and freedom for owners. For example, some licences mandate that source code for modifications must be made available to the community as a whole, while others allow modifications to be appropriated; some licences allow users to merge the licensed program with their own proprietary software, while others prohibit mixing with non-free or open source software; some licences contain special privileges for the original copyright holder over modifications made by other contributors; and finally, as mentioned in section 4.4.1 above (p.78), it is possible to dual-license a single program, so that customers have the option of buying commercial-licensed versions that are not open source.[111]

If we imagine a spectrum bounded by no licence at all at one extreme – that is, straight-out donation to the public domain (in the biotechnology context, this would be achieved by simple publication) – and standard proprietary licences at the other, the open source licence that lies closest to the public domain end (maximum freedom for users) is the Berkeley Software Distribution Licence (the BSD) and other BSD-style licences such as X and Apache. The BSD licence was originally developed to release non-commercial software developed as a byproduct

establish a contractual relationship, as discussed earlier the GPL is arguably not a contract, so the practical importance of this is unclear.)

[110] Brian Behlendorf, personal communication; the discussion that follows draws on Behlendorf (1999). For a detailed comparison of the characteristics of frequently used open source licences, see Fitzgerald & Bassett (2003), Table 1, pp.22-29.

[111] Bill Lard, in Rosen et al. (2003), p.61.

of university research; it continues the academic tradition of insisting on proper credit for contributors, but imposes no real restrictions on use of the licensed software.

Such a licence, of course, leaves room for proprietary strategies that free ride on contributions released under the BSD without contributing their own improvements back into the commons. This need not necessarily be a serious disincentive to developer contributions, especially in the biotechnology context, where (in principle if not always in practice) publication can block downstream appropriation by creating prior art.[112] However, historically such proprietary strategies have been perceived by many software developers as an abuse. As we have seen, the GPL is designed explicitly to prevent this abuse by insisting that enhancements, derivatives and tools that incorporate the technique are also released under the GPL. As Behlendorf points out, this essentially eliminates the option of making money through software value-adding, but the GPL could still be used as a competitive weapon to establish a platform that discourages competitive platforms from being created and protects the original developer's position as the leading provider of products and services that sit upon this platform. Behlendorf also notes that the GPL could be used for business purposes as a technology sentinel, with a non-GPLed version of the same tool available for a price (using dual licences).[113]

Further towards the proprietary end of the spectrum (maximum freedom for original intellectual property owners, fewer freedoms for users) lies the Mozilla Public Licence, or MPL; yet further on lies the Netscape Public Licence, or NPL. Like the GPL, the MPL requires that changes be released under the same licence, therefore making them available back to the development community. The NPL was developed by Netscape for open sourcing the Navigator Web browser, and contains special privileges that apply to Netscape, specifically the ability to relicence modifications authored by other contributors under a closed licence. The NPL experience highlights the risks to building an effective developer community associated with a licence that retains too many rights to appropriate contributions in the hands of a corporate sponsor; we return to this point in a later chapter (section 7.2.4, page 215).[114]

Multiple licences attached to a single technology

As in the biotechnology context where multiple owners control complementary intellectual assets, different licences may apply to different modules within a single program. For example, Red Hat Linux consists of about 2,800 modules,[115] and by one calculation, there are more than 17 licence types represented among them: about 65% are licensed under the GPL or Lesser GPL; about 17% are licensed under the MIT licence or its close relative the BSD; nearly 7% are licensed under

[112] I am indebted to one of my (anonymous) thesis examiners for suggesting this clarification.
[113] Behlendorf (1999).
[114] I am indebted to the same examiner for this point and form of words.
[115] Rosen et al. (2003), p.4.

the MPL; others have been released into the public domain.[116] The application of a mixture of licences to different parts of a single program can lead to transaction costs, especially for commercial players, relating to the need to identify which licence applies to which portions of the code; the difficulty of providing for click-wrap or other execution of two or more licences for one product based on collaboratively developed code; and different maintenance or warranty obligations applying to different portions of the code.[117]

The GPL: backbone of the open source movement

The GPL is by far the most commonly used open source licence – the "backbone of the open source movement".[118] As we saw earlier, the "viral" (or "inherited") nature of this licence – that is, the imposition through copyleft provisions of reciprocal obligations on authors of derived works – is its most striking feature.

Viral nature of the GPL Contrary to common fears, merely running software together with code licensed under the GPL does not "infect" that software: for ordinary users of binary programs, including commercial users, the GPL poses no unusual legal problems. Similarly, as noted above, users who modify code licensed under the GPL to meet the needs of their own organisation or its controlled subsidiaries are not required to distribute modifications or disclose sources; there is therefore no danger to any related trade secrets.[119] On the other hand, as we saw earlier, users who redistribute modified or unmodified sources, whether for profit or otherwise, must do so under the terms of the GPL, although even in such a case the option of using the Lesser GPL (mentioned above, p. 89) may apply to permit combining or linking of code licensed under the GPL with other software in such a way that no derived work is created and the aggregate software is not subject to either the GPL or the Lesser GPL.[120]

Borderline cases do exist: enforcement of the GPL may sometimes be tricky because, as discussed in section 4.4.1 (p. 81), the boundary lines of derived works in software are still somewhat uncertain. Although the general term is defined in copyright law, there have not been many cases elucidating exactly what constitutes infringement via creation of derived works. According to Webbink, the hardest cases are those in which an open source operating system has to be modified in order to allow proprietary applications to function; the resulting link between the operating system and the proprietary application is close enough to suggest that they may in fact be one program, not two, which would mean the GPL could apply to the proprietary application.[121] Rosen suggests that another difficult question is whether a manufacturer of hardware such as microchips or

[116]Webbink (2003), p.68.
[117]James (2003).
[118]Webbink (2003), p.6
[119]Ibid., p.7.
[120]Ibid., p.8.
[121]Ibid.

TV set-top boxes who embeds a GPL-licensed program in the hardware together with proprietary software is bound by the reciprocal obligations of the GPL, even though there is no interface to allow a user to modify the embedded code.[122]

This uncertainty may be a problem for a commercial licensor if there is third party technology tied up in its products; this issue is discussed in more detail in the next chapter. For now, note that community expectations are relevant to interpretation of the law relating to derived works. Fitzgerald makes the point as follows. According to case law, in order to establish whether a later work infringes copyright in an original work, the copyright owner must usually prove that the derivative use was not customary or reasonably expected, and that the owner was thereby denied an opportunity for compensation. But in the free and open source software world, developers know that the making of a derivative work is customary, and further, do not generally seek compensation for use of the original work in the creation of a derived work, but rather specific performance – that is, publication of the source code of the derived work.[123]

In addition to genuine uncertainty surrounding the creation of derived works in the software field, "FUD" – that is, "fear, uncertainty and doubt" deliberately circulated by organisations whose commercial interests are threatened by the spread of free and open source software licensing – also exists. This is relevant to the feasibility of translating open source licensing strategies into the biotechnology context because, while genuine uncertainty might be overcome through careful drafting of biotechnology licences, FUD may still have a strong enough effect to frustrate efforts to get such licences adopted. We will touch again on this issue in chapter 7.

Court interpretations of the GPL So far there have been no definitive court interpretations of the GPL (though there have been some obiter dicta to the effect that the GPL is an effective licence intended to restrict the manner in which software is distributed).[124]

The fact that the GPL has never been challenged in court is sometimes seen as a weakness, but could equally be regarded as evidence of the licence's durability. Given the hostility of some software industry players towards free and open source licensing, there is always the possibility of an intentional violation aimed at having the GPL declared invalid. It has been argued that, at least to the extent that the GPL is a copyright permission and not a contract, this strategy would backfire because if the licence were found to be invalid the violator would automatically be in breach of copyright. However, even if this were so, any player prepared to adopt an endgame strategy could still do considerable damage.

An example of such a threat is the current litigation between the SCO Group (previously Caldera Systems and Caldera International) and IBM.[125] SCO claims

[122]Rosen et al. (2003), p.44; James (2003), p.73.
[123]Fitzgerald & Bassett (2003), p.33.
[124]Webbink (2003), p.10.
[125]Bassett & Suzor (2003), p.126.

that by a series of corporate acquisitions reaching back to the original owner, AT&T, it is the owner of the software program UNIX, including code that was used to develop the Linux kernel. In its amended complaint, SCO seeks US $3 billion in damages, alleging that by copying or adapting code into Linux, IBM breached the terms and conditions contained in several licences relating to UNIX System V source code. SCO also alleges that IBM engaged in unfair competition in aiding development of Linux and that it misappropriated SCO's trade secrets relating to methods of running a UNIX based system on Intel processors in order to further development of the Linux kernel. In a counterclaim, IBM alleges that SCO breached its licence terms by purporting to terminate IBM's perpetual and irrevocable UNIX rights, that it has publicly misrepresented the legitimacy of IBM's Linux-related products and services in contravention of trademark legislation, and that it has also infringed four of IBM's software patents. In addition, IBM alleges that SCO has breached its obligation under the GPL (which it incurred by distributing Linux products) not to assert proprietary rights over Linux source code.

In connection with this litigation, SCO has announced that it plans to charge licence fees for commercial use of GNU/Linux systems.[126] Even though the open source community generally reject's SCO's allegations,[127] this claim has the potential to slow the uptake of open source software by corporations. The issue of the commercial appeal of open source software is dealt with in more detail in chapter 7; in the present context the relevance of the litigation is that if it proceeds to completion it may generate precedents on several issues that are currently uncertain in relation to the GPL, including classification of the GPL as a licence or a contract, discussed earlier; revocability of rights under the GPL – according to the FSF, software freedoms are not real if the developer of the software can revoke the licence without the user giving cause;[128] and enforceability.

4.5 Conclusion: the promise of open source

The previous chapter argued that the recent proliferation of intellectual property rights in biotechnology has caused a number of problems that could be at least partly resolved if industry participants and would-be participants had access to an unencumbered and affordable development toolkit. In this chapter we have seen that a mechanism for generating such a toolkit – that is, open source licensing and development – already exists in the software context. Open source is a strategy that has an extremely low barrier to entry: it can be adopted unilaterally by any industry participant, from an individual developer through to a major multinational firm. This strategy has been used to harness the innovative energy of large numbers of independent thinkers, in accordance with theories of opti-

[126] Ibid.

[127] See, for example, Moglen (2003).

[128] Free Software Foundation, "The Free Software Definition", http://www.gnu.org/philosophy/free-sw.html.

mal scientific production discussed in chapter 2, but – importantly, in the current environment of declining public funding for research and development – is not incompatible with commercial technology development.

The remainder of this thesis assesses the feasibility of transplanting the open source model into a biotechnology context as a partial solution to the problems canvassed in chapter 3. Chapter 5 explores whether open source licensing principles could be implemented outside the software sphere, in biotechnology. Chapter 6 outlines an analytical framework that allows us to generalise the principles of open source technology development, then presents a systematic survey of how these principles could be expected to operate in biotechnology research and development. Chapter 7 considers the commercial possibilities of open source biotechnology, including the likely impact on the industry if an open source strategy came to be widely adopted, and presents evidence of the seeds of an open source biotechnology movement already in existence.

Chapter 5

Biotechnology and open source licensing

5.1 Introduction

In chapters 2 and 3 we saw that intellectual property rights are increasingly used to restrict access to and use of biotechnology-related innovations. We also saw that this practice raises the overall costs of participation in ongoing research and development, thereby reinforcing structural problems within the biotechnology industry that detract from the social value of technological innovation in this field. Chapter 4 described how similar problems have been at least partially resolved in the computer software industry through the adoption of an "open source" approach by some industry participants. In the remaining half of this thesis, we explore the possibility of translating the open source model into the biotechnology context.

As we saw in chapter 4, "open source" is a broad term that simultaneously denotes a set of licensing criteria, a development methodology and a characteristic approach to the commercial exploitation of technological innovations. All are important aspects of the open source model, but open source licensing is fundamental because open source exploitation strategies rely on collaborative technology development, which in turn relies on licensing as a means of preventing defection from the collaborative effort. To a large extent, therefore, the feasibility of open source biotechnology depends on the "devil in the detail" of incorporating open source principles into biotechnology licences.

The binding power of an open source licence derives partly from the threat of legal enforcement and partly from the concrete articulation of terms of co-operation among developers who interact within a network of ongoing business and other social relationships, so that departure from those terms carries a clear cost in terms of the erosion of economically valuable social capital. In order to be effective, therefore, an open source biotechnology licence would need to be both legally enforceable and accepted by members of the relevant development network.

This means that drafting a usable open source biotechnology licence would require not only the application of expertise in a range of highly technical areas, but also an iterative program of community consultation. Proposing a suite of

model open source biotechnology licences is therefore beyond the scope of this thesis. Instead, my aim in the remainder of this chapter is to give the reader a sense both of the issues that would need to be resolved in creating workable open source licences in biotechnology, and of the process by which this might be achieved.

The chapter begins with a brief overview of conventional biotechnology licensing, necessary to place subsequent discussion in context. Next, I offer some ideas about the respective roles of technology developers, academic and practising lawyers and technology transfer professionals and corporate, government or philanthropic sponsors in developing functional open source biotechnology licences. The conclusion to this section suggests that the necessary process of iterative learning with respect to practical implementation of such licences could be accelerated by drawing on the experience of the open source software community, embodied in the principles of the Open Source Definition (OSD). The final section reports selected results of a comparison of these principles with conventional biotechnology licensing practice, conducted in order to determine whether open source biotechnology licensing would be broadly feasible and, if so, which areas would require most technical and community input. While these results are not claimed to be definitive, they may prove useful: so far as I am aware, this is the first time such a comparison has been systematically undertaken.

5.2 Conventional biotechnology licensing

By definition, licensing depends on the existence of proprietary rights. Three main types of proprietary or quasi-proprietary rights are relevant to biotechnology licensing: statutory rights (patents and plant variety rights), trade secrets, and personal property.

Patents are the most important form of protection for biotechnology-related innovations. General classes of patent claims that are relevant to biotechnology inventions include ordinary process and product claims as well as new uses of known products – a type of process claim – and compositions or formulations of biological materials – a type of product claim. Specific classes of patentable biotechnology inventions include classical microbial technologies, "new" biotechnologies based on recombinant DNA (genetic engineering) or hybridoma (cell fusion) technology, and therapeutic molecules used as drugs.[1]

Despite increasing use of such patentable biotechnologies in plant breeding, classical methods continue to be relevant. This means a variety developed using patentable methods may be protected under both patent law and plant variety protection laws; thus, in the plant biotechnology context, licences typically deal with both types of property rights.[2]

In contrast with plant variety protection, trade secret protection cannot overlap with patent protection because trade secrecy and patent laws impose oppo-

[1]World Intellectual Property Organization (1992), pp.27-29.
[2]Ibid., p.31.

site obligations with respect to disclosure. However, trade secrecy can be used to protect peripheral information surrounding a patented invention or to protect the early stages of development of an invention that is expected to become patentable at a later stage. Thus, trade secrecy and patent protection often coexist in relation to a particular technology.

The category of personal property rights is particularly relevant to biological materials. The preferred legal mechanism for transferring physical materials in this context is bailment, defined as the delivery of personal chattels on trust, usually on a contract (express or implied) that the trust shall be duly executed and the chattels redelivered in either their original or altered form as soon as the time or use for which they were bailed has elapsed.[3] In the case of biological materials, the obligation to return the goods is usually explicitly extended to progeny that is directly traceable to the original material (see below, section 5.4.4, p.127).

Biotechnology licensing is a multi-stage process. As we saw in chapter 3 (p. 38), the search costs involved in locating a suitable licensee or licensor can be substantial. Once the parties have found each other, there may be several rounds of negotiation between first contact and final signature. The process is generally documented in both formal and informal instruments including confidentiality or non-disclosure agreements, material transfer agreements, option agreements, term sheets or memoranda of understanding and, increasingly, agreements to negotiate.[4]

The key negotiated terms of a typical biotechnology licence agreement include provisions dealing with definitions of licensed subject matter, allocation of rights in derivatives of and improvements to the licensed technology, the degree of exclusivity of the licence (exclusive, sole or non-exclusive), field of use and territorial restrictions, sublicensing rights, responsibility for maintenance and enforcement of patents, warranties, indemnities and limitations of liability (especially in relation to infringement of any third party rights in the technology and in relation to product liability), regulatory approvals, term and termination of the licence and remuneration.[5]

In addition to these key terms, a typical biotechnology licence agreement will contain a number of formal clauses, as well as appendices or schedules (which may or may not be expressed to be an integral part of the agreement). Formal clauses may include an introductory provision, recitals, definitions and notices and execution clauses, together with "boilerplate" terms dealing with dispute resolution, force majeure, procedures for varying the agreement, termination, governing law, the exclusion of pre-contractual statements and confidentiality.[6]

A typical licence agreement incorporates provisions dealing with intellectual property rights and often also with trade secrets. Rights in personal property are usually transferred under a separate material transfer agreement (MTA). An

[3]Ibid., p.78.
[4]von Gavel (2001), pp.4-6.
[5]Ibid., pp.67-94 passim.
[6]Ibid., pp.40-57 passim.

MTA has two key functions.[7] The first is to define the extent and purposes of the transfer. Biological materials are difficult to control from a legal perspective because of their inherent ability to replicate, to be transferred from one organism to another, to be combined with other substances, to exist in different forms, to be modified and to be used to generate completely different substances.[8] Thus, an important task in defining the extent and purposes of the transfer of such materials is to distinguish between the original biological material and other related substances. The second key function of a material transfer agreement is to provide a technical description of the transferred materials sufficient to enable the recipient to practise the technology without having to invest substantial further resources in bringing the materials to a usable state. Both these functions are discussed further below (section 5.4.3, p.121; section 5.4.4, p.127).

5.3 Developing open source biotechnology licences

The material in this section, while based on discussions with interested industry participants, is not intended to be predictive or prescriptive. Rather, it is offered in support of the feasibility of open source biotechnology, as a demonstration that it is possible to envisage plausible solutions to the main problems that could be expected to arise in developing legally enforceable open source biotechnology licences that are acceptable to technology developers.

5.3.1 Licences must be accessible to technology developers

As we saw in the previous section, a typical biotechnology licence is a highly technical document, carefully drafted by specialists and incorporating a range of "boilerplate" provisions to deal with unexpected contingencies. By contrast, many open source software licences omit formal provisions that most lawyers would consider important.[9]

This informality is a cultural artefact of the particular institutional and historical setting in which open source licensing evolved. It is not so apparent in newer licences, and may eventually disappear altogether as open source software moves into the commercial mainstream and licences are scrutinised and overhauled by teams of corporate lawyers.

While careless or sloppy drafting of licence agreements is clearly undesirable, the informality of open source software licences has had some positive consequences. Technical legal language and clauses dealing with issues that are not central to the transaction generally make a licence more difficult to read and understand and less widely applicable, though they may make it easier to enforce. The absence of such technicality has almost certainly contributed to the widespread adoption of open source software licences. Thus:

[7] von Gavel (2001), p.8ff.
[8] Ibid.
[9] James (2003).

> The GNU GPL is designed so that you can easily apply it to your own program if you are the copyright holder. You don't have to modify the GNU GPL to do this, just add notices to your program which refer properly to the GNU GPL.[10]

By facilitating the direct involvement of technology users in formulating licence terms, the simplicity of open source licences has also contributed to their evolution and fine-tuning as instruments that accurately reflect software authors' collective understanding of the terms of open source collaboration. Apart from the cost of obtaining professional advice, a lawyer's role in protecting his or her client from legal risk means lawyers tend to be conservative in their general outlook. While the involvement of lawyers as norm entrepreneurs has been critical at various stages in the evolution of open source licensing,[11] the necessity of involving lawyers or other licensing professionals in the everyday execution of licence agreements would have been a considerable hindrance.[12]

Thus, although there is no question that open source biotechnology licences would need to be properly and professionally drafted, past experience suggests that a successful open source licence must also be easy to use. Indeed, the adverse consequences of an overly technical approach to managing technology transfer are already evident in the biotechnology context. For example, recall from chapter 3 (section 3.3.1, p.39) Eisenberg's description of a two-tiered pattern of exchanges of biotechnology research tools, in which technology transfer officials preside over formal legal agreements which are constantly undermined by informal exchanges among researchers.[13]

5.3.2 Model licences

One way to make open source biotechnology licences easier for technology developers to use would be to develop a suite of model licences. John Walsh et al., in their study of transaction costs in the biotechnology industry (see section 3.3.2, p.42), suggest that development of standard contracts and templates may be helpful in diminishing the costs of adjustment to effective intellectual property management by industry participants.[14] This approach has also been suggested in the context of negotiations to establish PIPRA (described in chapter 3, p.59) to counteract the possibility that introducing finer-tuned licensing practices might create more work for overstretched public sector technology transfer officials:

> One [idea] is to create a common set of procedures, of licensing agreements and so on, and to have a common database that they can

[10] Free Software Foundation, "What is Copyleft?", http://www.gnu.org/copyleft/copyleft.html, last accessed 17 December 2004.

[11] Stallman (1999).

[12] A norm entrepreneur is an individual or entity that seeks to promote or change a norm: Sunstein (1996), p.909.

[13] Eisenberg (2001), pp.242-243.

[14] Walsh & Cohen (2003), p.333.

> use – in other words, to provide resources that will allow them to do their job better. ... [We wouldn't be aiming for] one size fits all. But... once you have done one, it serves as a model for the next one.[15]

Walsh et al. further suggest that funding agencies such as the National Institutes of Health could play an important role in developing and encouraging the use of such standards. In the PIPRA case, this function is being performed by private philanthropies, primarily the Rockefeller Foundation; large corporations might assume a similar role, though in that case it would be important to ensure that smaller licensors are able to retain their independence.

While all such efforts are likely to be of some use, a certain degree of technicality is probably inevitable in biotechnology licensing due to the diversity of licensed subject-matter and the difficulty of imposing legal conditions on the use of living materials. For example, the National Institutes of Health Uniform Biological Material Transfer Agreement (UBMTA) – a standard contract developed for exactly the reasons and in the manner suggested by Walsh et al.[16] – is regarded by many as too legalistic and more cumbersome even than previously existing institutional material transfer agreements; as a result, it has not been widely adopted.[17]

An additional difficulty in getting standard licences adopted in biotechnology is that industry participants, especially commercial firms, are generally unwilling to commit themselves to a particular licensing policy, preferring to make decisions on a case-by-case basis. This was the reason for the failure of Stanford University's "master MTAs" initiative, intended to reduce negotiation costs by creating a single default agreement for each private company that had frequent dealings with the university.[18] A similar problem has arisen in the open source software context, where commercial players have been reluctant to make use of existing licences, instead creating their own and submitting them for certification to the Open Source Initiative. The proliferation of open source licences that are essentially minor variations on a theme – sometimes referred to as "the combinatorial problem"[19] – is of great concern to community leaders:

> Certification organisations are not allowed to discriminate; they lose their right to enforce the certification if they do. One of the problems that that has caused is that we have this ridiculous propagation of open source-approved licences. The really bad things about that

[15]Gary Toennissen, personal communication.

[16]On March 8, 1995, the NIH published the final version of the UBMTA for transfer of materials between non-profit institutions and an Implementing Letter for the Transfer of Biological Material: Uniform Biological Materials Transfer Agreement, 60 Fed. Reg. 12771 (March 8, 1995). The UBTMA allows signatory institutions to transfer materials to one another using a boilerplate Implementing Letter for the particular transfer, to be executed by the provider scientist and the recipient scientist.

[17]John Barton, personal communication; Kathy Ku, personal communication; see also Rai & Eisenberg (2003), p. 305.

[18]Kathy Ku, personal communication.

[19]Brian Behlendorf, personal communication.

> are first, that they are incompatible with one another in their terms – which fragments the community, and is really awful, and second, that practitioners of the art [of programming] are not attorneys and we are now giving them the burden of having to understand a whole lot of different licences.[20]

If an open source certification program is considered desirable in the biotechnology context, this problem could be avoided by adopting certification criteria requiring newly certified licences to be both fully compatible with existing licences and substantially innovative. Such an approach would result in a smaller set of licences, each with its own clearly defined range of applications.[21]

The Creative Commons copyright licensing initiative has found solutions to both these problems – irreducible technicality and diverse user needs – that could be applied in the development of standard open source biotechnology licences. The problem of technicality is overcome in the Creative Commons model by the introduction of multiple layers within a single licence agreement:

> The human readable form, the Commons Deed, [is] an icon that is hyperlinked to a plain language version of the licence that anyone can understand. Behind that is the code, the actual legal document to back up your licence in case of contention in court; this is the lawyer readable form. The machine-readable portion we are still trying to work out... .[22]

The problem of diverse user needs is solved in an equally user-friendly way. A copyright owner can go to the Creative Commons website and compose a suitable licence by clicking on a menu of options that relate to attributes of the licence regarding attribution, commercial use, and derivative works. (The default is to allow derivative works; the menu also includes a "share-alike" option analogous to copyleft.)[23]

5.3.3 Roles of licensing experts and others

The Creative Commons example also shows how lawyers might become involved in the development of open source biotechnology licences without disrupting or distorting the process. By providing concrete examples of workable licences that can be used to create different kinds of common pool regimes, Creative Commons is engaging in what Peter Drahos has described as "model mongering", an activity for which academic lawyers are well qualified.[24] It has been suggested that it may prove more difficult to involve patent lawyers in an open source biotechnology licensing initiative than it has been for the open source software movement

[20] Bruce Perens, personal communication.

[21] Ibid.

[22] Neeru Parahia, Open Source Biology workshop.

[23] See Creative Commons, "Creative Commons Licenses", http://creativecommons.org/licenses/, last accessed 21 December 2004.

[24] Braithwaite & Drahos (2000), p.519.

to attract interested and supportive copyright lawyers because of cultural differences between the different legal "tribes":

> Patent lawyers are like those guys in green eyeshades: very very technical. The copyright bar – especially on the West Coast – is a beast of a very different colour.[25]

However, the Creative Commons approach solves this problem by separating the roles of lawyers as norm entrepreneurs and as legal technicians. Academic lawyers, together with non-lawyer team members with close links to the community of prospective licence users, help to develop innovative licensing models, while technical drafting work is carried out largely by practising lawyers on a pro bono basis. Such work is perfectly compatible with lawyers' professional conservatism, but interesting and exciting compared with working on run-of-the-mill billable matters; at the time I visited Creative Commons there was an oversupply of volunteers. Thus, even though certain unusual legal personalities figure prominently in the history of open source software licensing, what would be needed in open source biotechnology if the Creative Commons approach were to be followed would be patent lawyers who like a technical challenge – surely not so hard to find. In the longer term, if the open source approach becomes established as a viable alternative to existing exploitation strategies in the biotechnology context, technology developers would be able to obtain professional advice on ordinary business terms: at least one firm of practising attorneys supports itself largely by billable work for the open source sector of the software industry.[26]

Model mongering on its own would not be sufficient to achieve a suite of legally enforceable and acceptable open source biotechnology licences, however; it is also necessary to identify intellectual property owners who are willing to experiment with innovative licensing models – to risk failure so that others can learn from their mistakes. Contrary to my own expectations, I did meet in the course of my fieldwork some potential "early adopters" or "lead users" of open source biotechnology licences: entrepreneurial scientists who see their technology not as a means of becoming rich or even famous, but as short-term leverage in creating new business models to help achieve long-term humanitarian goals.[27]

5.3.4 Learning from the software experience

The importance of trial-and-error testing ("selective learning", "learning by doing") of new licensing models is clearer when we consider that although the term "open source" was coined only a few years ago, the prehistory of open source stretches back at least to the end of World War II.[28] Thus, while it might apear

[25] Hugh Hansen, personal communication.
[26] Lawrence Rosen, personal communication.
[27] Anonymous informant: senior executive, small plant biotechnology firm.
[28] Raymond (1999); see also Levy (1984) and Weber (2004).

that the open source approach to technology licensing and development in the software context has been an instant success, there has been a long lead time on the development of some degree of consensus as to what licensing standards are necessary in order to achieve a more or less clearly defined technology commons. As Stephen Maurer's work on the failed Mutations Database Initiative shows, it cannot be expected that this kind of consensus would be easily reached among members of the biotechnology research and development community – although one way to accelerate the process would be to involve government, corporate or philanthropic sponsors with sufficient clout to impose a working consensus from the top down.[29]

On the other hand, developers of open source biotechnology licences do have the advantage of being able to draw on previous experience. Seen in this light, the proliferation of open source software licences is not a disaster, but an inspiration: a living record of all the false starts and few successes of twenty or so years of experimentation. The OSD itself was not written from first principles. Rather, in its first incarnation as the Debian Software Guidelines, it represented an attempt to articulate, through a process of community consultation, collective notions of how a particular intellectual commons should operate that had evolved through everyday experience among users of the Debian GNU-Linux distribution.[30]

Thus, existing open source licences and the OSD contain in their texts a wealth of experience about how open source licensing terms function in the software context as an incentive mechanism for capturing contributions to a common pool resource.[31] Even though not all of this experience will be relevant in the biotechnology context,[32] it is certainly a valuable resource that should not be overlooked. The only difficulty is that in its present form, the information contained in these documents is not readily accessible to the biotechnology research and development community.

In the next section, I aim to address this problem by providing an overview of the most important similarities and differences between conventional biotechnology licensing and the OSD. While future research could usefully focus on particular open source licences (for example, the GPL),the OSD has been chosen for this first comparison because it is itself an attempt to articulate general principles, so in effect, part of the work of generalising to the biotechnology context has already been done.

[29]Maurer (2001). This issue was discussed at length at the Open Source Biology workshop.

[30]Bruce Perens, personal communication.

[31]For a definitive discussion of the concept of a common pool resource, see Ostrom (1990).

[32]Recall from chapter 2 Hilgartner's observation that access practices are most intensively shaped at levels of research that can be defined in terms of a characteristic data stream: section 2.4, p. 14.

5.4 Biotechnology and software licensing compared

5.4.1 Conventional and open source licensing in biotechnology and software

Software and biotechnology licensing practice share certain features that are not necessarily common to technology licensing in general. For example, both software and biotechnology are relatively new and fast-evolving technologies, and both have expansive field-of-use and territorial applications. Further, as we saw in chapters 2 and 3, most biotechnologies are in fact not single technologies, but are made up of several components that may be subject to multiple overlapping proprietary claims; similarly, most software programs are only usable as part of a larger package of programs that are normally protected as separate pieces of property.

Despite these common features, there are important differences between software and biotechnology licensing. In this thesis I have deliberately avoided limiting the definition of the term "biotechnology", even though this would allow for greater analytical precision, because to do so would require ongoing categorisation of technologies for the purpose of different aspects of the discussion and risk losing touch with the broader debate. However, especially in relation to licensing, it is important to bear in mind Hilgartner's point that access decisions are highly contingent upon the nature of the technology in question (section 2.4, p.14). Compared with software licensing, biotechnology licensing deals with a much broader range of technological subject matter, and biotechnology licences as a class are therefore inherently more varied than software licences.

The same is true of the manner in which the licensed subject matter is protected. Even though both software and biotechnology have diverse proprietary protection implications – typical licence agreements in both contexts deal with more than one type of property or quasi-property right – the range of permutations and combinations in biotechnology licences is greater than in software, partly as a consequence of the different commercial functions performed by licences in the two fields (see below). As we saw in chapter 3, the inherent complexity associated with different forms of legal protection for biotechnology-related innovations is often compounded by uncertainty as to the scope and validity of particular proprietary rights.

Perhaps the most obvious difference between software and biotechnology licensing is the degree of uncertainty involved in biotechnology licensing due to peculiarities arising from the nature of living materials. Attempts to reduce this type of uncertainty tend to increase the technicality of a licence. In addition to pecularities mentioned in the previous section, the complexity of living organisms gives rise to difficulties of precise definition: while biotechnology licences routinely contain definitions of "materials", "products" and "technology" as well as of patents and other proprietary rights, drafting these definitions is not a rou-

tine matter.[33]

All of these factors point to a higher degree of complexity associated with biotechnology licensing compared with software licensing (some implications of this complexity in relation to drafting usable licences are explored further below). However, the fundamental difference between conventional software and biotechnology licences is that they typically serve different commercial purposes. Recall from chapter 4 that conventional commercial software is developed in "cathedral" style, that is, in accordance with a single architectural vision (even if, as with many famous cathedrals, development takes place over a long period under the direction of several architects and reflects a number of different architectural styles). Access to the source code is restricted to firm employees and contractors, and in consequence, the software can only be modified or improved by insiders to the firm.[34] Conventional software licences of the kind described in the previous chapter are designed to enable the software thus developed to be marketed to users as a final product, as if it were a manufactured good.[35] In other words, intellectual property in conventional commercial software is generally used to facilitate a product market (see section 2.8, p.26). In biotechnology, by contrast, product development is usually too large and complex a task for even the best resourced industry participant to undertake on its own, so different entities colonise different phases in the product value chain, from basic research to regulatory approval and marketing; technology is often licensed at an early stage of development, before the precise nature and utility of the product is known and sometimes before it can be protected except by trade secrecy.[36] In this context, the function of a licence agreement is not to allow the "sale" of a product to the end user – though some biotechnology licences, such as seed-label contracts, do perform this function – but to facilitate the integration of valuable information from a range of sources by establishing, not a product market, but a co-operative partnership.[37]

In this sense, the open source approach is closer to conventional biotechnology licensing than to conventional software licensing. The key *difference* between open source and conventional biotechnology licensing relates to the balance struck between incorporating external contributions to technology development and restricting general access to intellectual property in order to obtain some benefit (licensing revenue, cross-licensing rights or other concessions) in exchange for granting specific access. Individual biotechnology licences support a range of compromises between these two goals, but in general, from a licensor's perspective, the aim of a conventional biotechnology licence is to retain maximum control over the technology while allowing outsiders just enough access to permit whatever collaboration is necessary to move the technology along the

[33]World Intellectual Property Organization (1992), p.67.

[34]von Krogh & von Hippel (2003).

[35]Raymond (2001), chapter 5: "The magic cauldron".

[36]World Intellectual Property Organization (1992), p19.

[37]Recall the discussion in chapter 2 of Woody Powell's work on innovative networks in biotechnology (section 2.8, p.29; see also Arrow (1962).

value chain. In this model, exclusivity and sublicensing provisions control who is entitled to exercise the licensed rights, while field of use and territorial restrictions set limits on the conditions under which those rights may be exercised. Unsurprisingly, these terms are often heavily contested in licensing negotiations,[38] but even where there is no substantial conflict of interest between the parties, the necessity of imposing detailed structure on an inherently fluid data stream inevitably raises the cost of the transaction.

By contrast, as we saw in chapter 4, the open source approach is to permit full access to and use of the technology by (in Lawrence Rosen's words) "anyone, anywhere, for any purpose". In other words, in open source licensing the scales are tipped all the way towards maxmising contributions to technology development, leaving (almost) no room for the licensor to capture benefits that depend on restricting access to intellectual property. The qualification is necessary because copyleft-style terms do rely on the exercise of exclusive intellectual property rights, but the point remains that in this model the exclusive right serves the purpose of achieving the broadest possible participation in ongoing technology development, rather than creating excludability and rivalry-in-use so that the technology may be treated as a private good. The transaction costs of open source licensing should be much lower than those associated with conventional biotechnology licensing because even though the licensor must still decide which portion of the data stream to make available for collaborative development, there is no need for complicated boundary-setting beyond that point.

How does this fundamental difference between open source and conventional biotechnology licensing play out at the level of licence terms? The remainder of this section seeks to answer this question in sufficient detail to show that technical issues that could be expected to arise in constructing legally enforceable open source biotechnology licences would not be insurmountable. (A comprehensive legal analysis of these issues would require expertise in a range of highly technical subject areas and is beyond the scope of this thesis.)

The present analysis is based on information obtained during fieldwork interviews and the results of a quasi-technical comparison of conventional biotechnology licensing principles (drawn from a World Intellectual Property Organisation publication on biotechnology licensing and from licensing executive society tutorial materials) with the elements of the OSD, canvassed in detail in the previous chapter.[39] The structure of the discussion corresponds roughly to the three first and most important elements of the OSD, dealing with free redistribution, access to source code and rights in derivative works.

5.4.2 Promoting broad participation in technology development

In his discussion of commons-based peer production, Yochai Benkler argues that, under appropriate conditions, this mode of production will have systematic ad-

[38] World Intellectual Property Organization (1992), pp.67-69.

[39] World Intellectual Property Organization (1992); von Gavel (2001). See section 4.4.1, p.77.

vantages over other modes.[40] The reason is that self-selection of participants in a peer production model is better at identifying and assigning human capital to information and cultural production processes because it loses less information about who the best person for a given job might be.[41] In addition, says Benkler, there are substantial increasing returns in terms of allocation efficiency to allowing larger clusters of potential contributors to interact with large clusters of information resources in search of new projects and opportunities for collaboration; removing property and contract as organising principles of collaboration substantially reduces transaction costs.[42]

In this section we consider how open source licensing promotes self-selection of participants in collaborative production. We then consider some of the implications of allowing self-selection that would be relevant to an intellectual property owner's decision whether to adopt an open source exploitation strategy.

Elements of the OSD that promote self-selection of licensees

The main element of the OSD that promotes self-selection of participants in open source development is the free redistribution requirement (paragraph 1). This goal is also supported by the prohibitions on discrimination (paragraphs 5 and 6) and the requirement regarding distribution of copies of the licence agreement (paragraph 7).

Free redistribution In a typical biotechnology licence, the grant of rights may be expressed to be exclusive, sole or non-exclusive, with the additional possibility of different degrees of exclusivity in different fields of use or territories. With respect to sublicensing, the usual arrangement is that a licensee can sublicense to its affiliates without the licensor's consent, and to others only with the permisson of the licensor.

These aspects of conventional biotechnology licensing practice are inconsistent with the free redistribution requirement of the OSD. Free redistribution means that the licence must be entirely non-exclusive and that the licensor is prohibited from imposing any restrictions on the licensee's ability to sublicense the assigned rights. The overall effect of this requirement is to prevent the licensor from controlling the number or identity of people who have access to the technology.

As noted above, conventional biotechnology licences lie along a spectrum between maintaining control for the sake of generating direct return from ownership of intellectual assets and encouraging broad participation in technology development. At the end of the spectrum closest to open source, the technology is non-exclusively licensed to all comers for a nominal fee. A non-exclusive licensing strategy is most common where the licensor has an interest in or need for further development of the techology; the clearest example would be that

[40] Benkler (2002), p.381.
[41] Ibid., p.373 and p.376.
[42] Ibid., p.375 and 377.

of a university seeking to promote the development of a pioneer or fundamental technology, as in the case of Stanford University's licensing of the patented Cohen-Boyer recombinant DNA technology. On the assumption that some of the same considerations would apply to the decision whether to adopt an exclusive or non-exclusive licensing strategy as to the decision whether or not to go open source,[43] I asked the Director of Stanford University's Office of Technology Transfer whether it would ever be appropriate from a technology development perspective to adopt an exclusive licence in relation to an early-stage technology with a broad range of potential applications. The answer was that while some such technologies are immediately useful to a large number of potential licensees, others need a "champion" to devote resources to developing them to that point, in which case a period of exclusivity may be appropriate. The example given of a technology where non-exclusive licensing would be preferred was a monoclonal antibody, where "all you need is a few months to grow the clones, isolate the antibody and put it in bottles".[44]

The reference in this context to monoclonal antibodies is interesting in light of Cambrosio and Keating's account of the development of hybridoma technology, which together with the discovery by Cohen and Boyer of gene splicing techniques is often regarded as the basis of modern biotechnology.[45] Cambrosio and Keating highlight the fact that the transformation of monoclonal antibodies from an esoteric technique used in only a few laboratories to a tool with widespread clinical, industrial and scientific applications was not automatic but involved substantial investments; although the technology was never patented, in its initial stages it was "championed" by individual scientists and commercial firms. The history of this technique confirms that there is a stage of development prior to which a non-exclusive or open source approach is unlikely to be effective, and that active promotion of the technology beyond the local network in which it first emerged will usually be required for it to reach that stage. However, it also shows that proprietary exclusivity is not the only way to ensure a new technology reaches the point where it can be taken up and improved upon by an extended network of users. In fact, as we will see in chapter 7, provision of an already-useful technology base is well understood within the open source software community to be a pre-requisite of successful open source development (section 7.3.1, p.218).

No discrimination against particular people or groups As we saw in chapter 4, the main rationale for the OSD prohibition on discrimination with respect to the identity of licensees is the belief that "to get the maximum benefit from the process, the maximum diversity of persons and groups should be equally eligible to contribute to open sources".[46] Besides being inconsistent with the broad

[43]This analogy was suggested by Karl Handelsman of CMEA Ventures.

[44]Kathy Ku, personal communication.

[45]Cambrosio & Keating (1998).

[46]Open Source Initiative, "The Open Source Definition" (Version 1.9), http://opensource.asti.dost.gov.ph/docs/definition.php, last accessed 21 December 2004.

principle of maximising control in conventional biotechnology licensing, this aspect of the OSD is in direct conflict with the imposition of territorial restrictions, a common feature of biotechnology licences.[47]

There are essentially two reasons why territorial restrictions are normally included in a biotechnology licence.[48] The first is to accommodate differences in legal systems and business practices across territorial boundaries (the second is discussed under the next heading). It might be supposed that the inability under an open source licensing regime to impose territorial restrictions for this purpose would create more difficulty in biotechnology than it does in software because of the different primary legal protection regimes in the two fields, the argument being that copyright law is more globalised than national patent systems and therefore patent licences need to be finer-tuned to the countries in which the parties operate. Recently, however, harmonisation of intellectual property principles under TRIPS (see chapter 3, p.48), as well as the introduction of WIPO model laws in many developing countries adopting patent legislation for the first time,[49] means that the basic rights of a patent holder tend to be the same from one territory to another.

A number of points may nevertheless cause difficulties in relation to cross-border licensing of biotechnological inventions under an open source licensing regime. All of the following have been raised in discussions of the feasibility of open source licensing in biotechnology.

One subset of issues is the variable enforceability of intellectual property rights from one jurisdiction to another. In the software context, the Open Source Initiative has not been prepared to approve the Sun Community Licence (discussed in chapter 4) because in attempting to address this problem it falls foul of the OSD. Similar issues do arise in biotechnology, particularly in many developing countries, where patent protection is a recent development (within the last decade): while the legislation itself is not necessarily problematic from an intellectual property owner's perspective, implementation is a "completely different story".[50] A related set of issues arises from differing consumer protection regimes in different countries. For example, in some countries, the law may forbid certain types of disclaimers, leaving licensors vulnerable to a range of actions despite being protected on the face of the licence.[51]

A further possible cause of technical difficulties arising from licensing across territorial boundaries relates to export rules, which vary from one country to another. Most biotechnology licences specify which country's rules will apply,[52] but although this is prohibited under the OSD, an easy solution would be to refer to

[47]World Intellectual Property Organization (1992), p.69.

[48]Ibid.

[49]See World Intellectual Property Organization Co-operation for Development (Intellectual Property Law) Department web page, http://www.wipo.int/cfdiplaw/en/, last accessed 22 December 2004.

[50]Francisco Reifschneider, personal communication.

[51]James (2003), p.77.

[52]World Intellectual Property Organization (1992), p.81.

the relevant jurisdiction in general terms (for example, "the licensor's country of origin") instead of by name.

One point which sometimes causes concern is that an OSD-compliant biotechnology licence could not name specific groups or people suspected of being bioterrorists as being prohibited from becoming licensees or receiving the licensed technology. This is true, but does not mean there could be no defence against "malicious people getting hold of a biotechnology and using it to develop bio-weapons".[53] Any licence exists within a framework of other laws that may prohibit certain groups from having access to certain technologies. The drafting solution is the same as for export restrictions: the licence can simply express what is true in any case, that the parties must comply with applicable laws in exercising their rights and obligations under the licence.

While these points all indicate the need for careful attention to detail in implementing an international licensing standard such as open source biotechnology would aspire to be, they do not demonstrate any insurmountable technical difficulty. Cross-border licensing issues are not peculiar to an open source approach; any problems would have plenty of precedents and could presumably be solved given appropriate input from people with the necessary skills and knowledge (see discussion below). The only serious concern is that the resulting licences might be so technical, or ongoing transaction costs so high, that potential contributors to an open source biotechnology development effort would be discouraged from participating.

A possible solution is that adopted by Creative Commons in relation to its suite of standardised copyright licences, which are extensively used to assign and protect rights in web-based cultural content (above, section 5.3.2, p.101). Given the aim of facilitating the exchange of cultural goods via the Internet, expansion of the Creative Commons licensing model so that it can be used by copyright authors outside the United States has been a major focus of the Stanford University-based initiative. In porting licences to different international jurisdictions, Creative Commons has relied on the multi-layered format of its licences, in which the terms are expressed in "human-readable", "lawyer-readable" and "machine-readable" form; human-readable and machine-readable versions remain unchanged from one jurisdiction to another, while the lawyer-readable version is adjusted to take account of different legal environments.[54] As discussed earlier in this chapter (section 5.3), a similar approach could be adopted in relation to open source biotechnology licences to allow the underlying legal provisions of a licence to be changed while preserving a universally applicable, user-friendly licensing option for non-lawyer participants.

No discrimination with respect to fields of endeavour The second reason why territorial restrictions are normally used in conventional biotechnology licences is to ensure optimal commercial exploitation of the technology, important both in

[53]Roger Brent, Open Source Biology workshop.

[54]Neeru Parahia, Assistant Director of Creative Commons, Open Source Biology workshop.

order to generate maximum royalty revenue and to promote technology development.[55] The same basic rationale underpins the imposition of restrictions on field of use, often by reference to individual patent claims.[56]

Field of use restrictions are common in biotechnology licensing and patent licensing generally. The field of use clause is often the most contentious and difficult-to-draft part of a biotechnology licensing agreement, both because of uncertainty as to whether all valuable applications of the technology have yet come to light and because this is an area where the parties' interests are likely to come into conflict: the licensor will usually want the field drawn narrowly, while the licensee will want it drawn broadly.[57] The reason field of use restrictions are important for the ongoing development of many biotechnology-related innovations, especially pioneering or fundamental technologies, is that the breadth of possible applications means no single licensee is likely to have the capacity to realise the technology's full potential. Granting exclusivity to a single licensee in all fields puts pressure on the licensee to work the licence in diverse areas and across business sectors: in general, if the licence is exclusive, optimal exploitation is more likely if there are several licensees with different fields of use.[58]

As we saw in chapter 4 (p.84), an open source software licence may not discriminate with respect to the field of endeavour in which the licensed technology may be used (this corresponds to the reference to "any purpose" in Rosen's formulation of the open source approach). Translating open source licensing principles into biotechnology would presumably therefore entail a prohibition on field of use restrictions. Given that the primary purpose of field of use restrictions is to carve up the market for a technology in order to allow multiple exclusive grants in different fields, this may be less of a problem than it at first appears: open source licences are of necessity non-exclusive, so the danger of granting too broad an exclusive right to a particular licensee does not exist under an open source model.

On the other hand, field of use restrictions, together with territorial restrictions, may be a useful tool for making technology that would otherwise be bound up in exclusive licences more available for public interest and broader commercial use. Recall from chapter 3 the recent establishment of a collective intellectual property management regime for agricultural biotechnology, the Public Intellectual Property Resource for Agriculture (PIPRA: see p.3.5.4, chapter 3), by a group of land grant universities in the United States. One of PIPRA's primary aims is to overcome the fragmentation of public sector intellectual property ownership by identifying residual rights retained by members who have (partly as a result of a past lack of sophistication in relation to intellectual property management) assigned unnecessarily broad exclusive rights in important technologies to major commercial firms.[59] One of the architects of the initiative explains the importance

[55]World Intellectual Property Organization (1992), p.69.
[56]Ibid., p.67.
[57]Ibid.
[58]Ibid., p.68.
[59]A sole licence grant allows both licensor and licensee to use the licensed technology; an ex-

of field of use and territorial restrictions in this context:

> So we start by asking our members: "If it is exclusively licensed, tell us how you cut the deal... . Did you just sell them the farm, or did you get more specific?" And this is [an essential part of the] initiative: [to] hold each other accountable to a better set of licensing standards.... Best practice includes partitioning of patents. If you go and license something like your agrobacterium technique, license it just for cotton, or better, for cotton in the US, or even better – if you can – define which varieties, or if you can, constrain it to varieties owned by the licensee company in the US. The more you can constrain the space of the technology grant, the more is still left over [that you may choose] to put into the commons.[60]

Thus, the value of such field of use restrictions in terms of achieving wider access to key biotechnologies may outweigh the value of keeping to a strict analogy with open source software licensing by directly translating the criteria set out in the OSD.

Such a pragmatic approach would be consistent with that adopted by leaders of the open source software community in relation to patented code. The community objects to field of use restrictions in software patent licences because such restrictions are perceived as capable of insidiously undermining freedoms granted in relation to the same code under an open source copyright licence.[61] However, even patent holders that are highly supportive of open source copyright licences prefer to keep tight control over patent rights because of uncertainty as to their value:

> A company will allow the use of a patent for implementing what they see as a rather narrow specification, and all of a sudden it is realised that that same claim can be used to cure cancer. Now suddenly it's not just a $25 decision about whether to allow people to implement a standard; it's whether or not the company is going to get the $400 billion that will come from the cure for cancer. As a matter of practical reality, the likelihood that a patent that is useful for implementing a standard is also going to have great value in some other area is miniscule; but when companies are granting patent licences, they don't dare

clusive licence grant means it may only be used by the licensee, so granting exclusive rights in research tools means researchers at the university that developed the tool can no longer use it without the licensee's permission.

[60]Greg Graff, personal communication.

[61]"'Field of use' restrictions are... legally incompatible with section 7 of the GNU General Public License, [which] is intended to prevent the imposition of side restrictions (for instance, by patent licenses) which would deny the freedoms that the GPL itself gives you. If the software license does nothing to prevent this, you can find yourself in a situation where the program's license appears to give you freedom, but this freedom has been taken away by restrictions not stated there." Free Software Foundation, "Position on W3C Patent Policy", http://gnu.fyxm.net/philosophy/w3c-patent.html, last accessed 22 September 2004.

> preclude the potential blockbuster. ... No one is going to give up what they don't understand.[62]

In other words, precisely the same problem we would anticipate in the biotechnology context under a version of the OSD applicable to patent licences does in fact arise in software wherever code is protected by patents as well as copyright. The approach of open source community leaders to this situation has been to campaign for maximum breadth of patent licences, while remaining willing to compromise for the sake of workability. Thus, many open source licences, including the Apple, IBM and Mozilla licences, have field of use restrictions in their patent grants.[63] From the perspective of the free and open source community, the recent World Wide Web Consortium Patent Policy also represents a compromise: patent holders must licence patents that are essential to implementation of a web standard royalty-free to all comers, but may impose field of use restrictions such that the licence only covers standards implementation and not other uses of the patent.[64] The author of the OSD, Bruce Perens, affirmed that a similar approach might be necessary in the biotechnology context. Alluding to the range of Creative Commons licences, he pointed out that although some follow a strict open source model, others do not, yet overall the results are still useful; an open source biotechnology community might also want to modify some elements of the OSD to achieve its ultimate goals.[65]

Distribution of licence The goal of facilitating participation in technology development by a large and diverse group of contributors is also supported by other elements of the OSD. Recall that paragraph 7 of the OSD says that the rights attached to the licensed program must apply to all to whom the program is redistributed without the need for execution of an additional license by those parties. The rationale is that everyone who has access to the program should have it on the terms defined by the original licence – that is, that the freedom of a second generation of licensees should not be diluted by new restrictive terms introduced by the first generation of licensees. Paragraph 10 supports this requirement by ensuring that the licence can be made binding on the technology recipient through a proper contractual assent without hindering the evolution of the technology by imposing technical restraints on how this assent is manifested.

In the biotechnology context, some combination of approaches analogous to the "click-wrap" and "shrink-wrap" methods may be appropriate when the technology is being transferred partly in tangible form; external tear-open or "bag-label" licences are already used for some biological materials, such as seeds. In any case, there is no reason to suppose that the software controversy surrounding manifestation of assent would arise in relation to open source biotechnology

[62]Lawrence Rosen, personal communication.

[63]Ibid.

[64]World Wide Web Consortium, "W3C Patent Policy", 5 February 2004, available at http://www.w3.org/Consortium/Patent-Policy-20040205/, last accessed 22 December 2004.

[65]Bruce Perens, personal communication.

licences, as such licences are clearly contracts and any practical problems could be minimised with sufficiently careful drafting.

Consequences of allowing self-selection of licensees

It is clear from this discussion that although translating those elements of the OSD directed at removing barriers to access for all potential users of a licensed technology would raise some technical issues, none of these is likely to constitute a serious obstacle. The real question is whether the prospect of lifting restrictions on access to and use of intellectual property is likely to be attractive to biotechnology licensors. Ultimately, a licensor must choose the exploitation strategy that best suits its overall mission. This calculation is discussed further in chapters 6 and 7; in this section, we consider some of the implications of allowing licensees to self-select, with continuing reference to the comparison between the elements of the OSD and the provisions of a typical conventional biotechnology licence.

Remuneration Clauses dealing with remuneration are an important part of most biotechnology licensing agreements,[66] reflecting the conventional emphasis on intellectual property as a private good. A typical licence provides for two kinds of remuneration: a one-off or upfront licence fee, and ongoing payments linked to the licensee's exercise of rights relating to the technology. [67]

The free redistribution clause of the OSD explicitly prohibits the latter type of remuneration because requiring payment is one way of restricting the licensee's exercise of the relevant intellectual property rights (in the software case, the rights to copy, modify and distribute). Thus, a strictly OSD-compliant biotechnology licence would presumably prevent a licensor from recovering ongoing royalty-type licensing revenue. On the other hand, as we saw in chapter 4 (section 4.4.1, p.77), the OSD does not prohibit the charging of a one-off licence fee, although in a practical sense it limits such fees by ensuring that every licensee has the right to distribute the technology in competition with the original licensor. In the software context, some distributors are able to charge for copies of programs that are available *gratis* because of the perceived convenience or superior quality of the particular distribution, for example, Red Hat Linux.[68] Licensors might actually find it easier to retain this type of competitive advantage in the biotechnology context: the relatively uncodified nature of the technology, together with the peculiarities of living organisms detailed earlier in this chapter, means many biotechnologies are more difficult than software code to copy accurately, and as a result licensees may be willing to pay to deal directly with the entity with the longest experience of the technology, or to obtain biological materials direct from the original source instead of from other licensees. Thus, it is too simplistic to say that there would be no further possibility of obtaining any licensing income

[66] World Intellectual Property Organization (1992), pp.44-51; 92.
[67] Ibid., p.92.
[68] Young (1999).

under an open source approach. Nevertheless, such an approach *would* reduce a biotechnology licensor's direct revenue stream to that which could be obtained by charging one-off fees in competition with its own licensees.

The next question is whether this excludes the possibility of open source licensing in biotechnology. It might be argued that it does, on the basis that patent protection of biotechnology inventions is much more costly than copyright protection of software works. Copyright protection is free, whereas obtaining and maintaining patent protection, especially in more than one jurisdiction, entails payment of substantial upfront and ongoing fees. Obtaining patent protection takes time, whereas copyright arises immediately upon embodiment of a protectable work. Prosecuting a patent application requires substantial technical expertise, whereas copyright is automatic; even though registration of copyright ownership has some advantages, the procedural requirements are less onerous than for patents. Litigation to enforce patent rights is also notoriously expensive.[69] Remuneration provisions in biotechnology licences are often set up in such a way that these costs are written off against ongoing licensing revenue;[70] it may therefore be suggested that to deprive patent holders of this income stream would mean they could not afford to obtain the intellectual property rights that are as critical to an open source approach as to the conventional approach.

Part of the answer to this objection is rooted in the fact that an open source strategy, like the conventional approach to biotechnology licensing, is ultimately based on economic self-interest. An open source approach will only be considered in preference to the conventional approach by a commercial player who calculates that the loss of licensing income or other benefits obtained through granting limited access to a patented technology would be outweighed by gains from faster, cheaper, or better technology development under the open source model. The cost of obtaining patent protection is the same in both cases and therefore does not tip the scales either way;[71] if the overall return to innovative activity, taking into account all possible revenue streams, would be greater using an open source licence as against a conventional licence, it would not matter if a particular revenue stream is diminished or cut off entirely.

This argument only applies, of course, if the trade-off is between the conventional and open source approaches to intellectual property management. If the trade-off is between an open source approach, which depends on intellectual property ownership, and simple publication of an invention, the higher cost of protecting biotechnology-related intellectual property relative to software could mean that open source biotechnology licensing is less likely to be practicable than open source software because fewer potential contributors would have the resources to participate. The issue of how big a pool of contributors is required for a successful open source development effort is discussed in detail in chapter 6 (section 6.6.2, p.189); however, information gathered during fieldwork in-

[69]For example, see Ellis (2000).

[70]World Intellectual Property Organization (1992), pp.44-51.

[71]In fact, it is arguable that enforcement costs would be lower under an open source regime: see next section.

terviews suggested that most institutions capable of conducting biotechnology research and development are also capable of meeting the costs of intellectual property protection, provided they see value in obtaining such protection.[72] Under an open source model, such value would derive largely from the ability to use copyleft-style licensing terms to guarantee continued access to the most advanced version of the evolving technology (see below); presumably, given the cost of patent protection, non-copyleft open source licences (analogous to the Berkeley Software Distribution licence: see section 4.4.2, p.88) would be less often used in the biotechnology context.

It is worth noting that in my fieldwork discussions I did not generally receive the impression that those who raised the issue of the higher cost of patent protection relative to copyright had consciously considered these distinctions. Rather, it seemed that most were assuming open source licensing would preclude commercial exploitation altogether, at least in the biotechnology context. One attorney's reaction is representative:

> There is a strong intuitive case to be made that open source works in the academic-to-academic... context. [But] that is a highly unique situation and... at some point down the line it is going to veer into the commercial sector, and...[w]hen it does that, then the model breaks down.[73]

Those who expressed such sentiments may have acknowledged the existence of such strategies in principle, but dismissed the possibility of obtaining any substantial benefit from them in practice, either from the point of view of the speaker's own institution (which might not have been in a position to generate income by alternative methods), or with respect to the biotechnology industry as a whole. Whether sufficient income could in fact be extracted from alternative revenue streams in the biotechnology context is a practical question that presumably has different answers in different circumstances. We consider it further in chapter 7.

Pedigree Determining the ownership or pedigree of the technology to be licensed is a critical aspect of technology transfer in any industry. As is apparent from the discussion in chapters 2 and 3, it can be particularly complex in biotechnology because the complementary and cumulative nature of innovation in this field means that the licensor has often developed the technology using proprietary inventions or materials obtained from third parties. Further, as we saw in the discussion of transaction costs in chapter 3, title may be obscured by unauthorised "unofficial tier" exchange of information and materials among researchers and by restrictions on commercialisation (for example, limitations on the duration of licences or on the right to grant exclusive licences) imposed as a condition of external funding.[74] Thus, checking the pedigree of a biotechnology may in-

[72] Andrzej Kilian, personal communication.

[73] Anonymous informant: partner, major US law firm.

[74] See section 3.3.1, p.39.

volve reviewing MTAs and funding contracts and interviewing researchers to discover the source of materials used in development across several different research groups located in different industrial or academic organisations.[75] Concerns regarding the pedigree of the licensed technology are normally addressed in the warranties and representations section of the licence agreement. A typical biotechnology licence contains a warranty by the licensor, often supported by an indemnity, that the licensee's exercise of rights under the licence will not infringe the intellectual property rights of any third party.[76]

In the software context, many businesses are wary of open source technologies because they are concerned that they will not be able to pass a clear title to their own customers if some part of the open source code has been contributed by someone who did not actually own it; even though under an open source licence there would be no obligation to indemnify customers, "try convincing a big multinational... that they don't deserve an indemnity".[77] This situation need not result from deliberate dishonesty or mistake as to authorship; it can and does arise where an employee submits code he or she has written in the course of employment without first obtaining the employer's permission. A related concern for commercial entities in the software context is that without the ability to track ownership of contributions, it is usually impossible to know on what licence terms any particular contribution was made, so that there is a risk of accidentally incorporating copylefted code into proprietary programs and, if the licensor is unable to demonstrate which licence applies to which section of code, of being unexpectedly obliged to publish the source code of the whole program.[78]

One way to minimise these problems in the open source biotechnology context would be to start with well designed and documented processes for submitting contributions, so that the origins of each part of a collaboratively developed technology could be readily identified. (This would be important in any case in the biotechnology context to facilitate peer review of contributions of experimental data obtained using protocols that may differ slightly from one laboratory to another.) This would not eliminate the need for contributors to perform a title check before making their submissions, but as this is a necessary preliminary to any biotechnology licensing, it need not constitute a special obstacle in relation to open source biotechnology. In light of the second concern referred to above, it would also be desirable to limit the proliferation of open source licences – a precaution that has been suggested by open source software community leaders in any case (see above, section 5.3.2, p.100). Another possibility would be to relax the OSD analogy sufficiently to set up a central registration facility, similar to that

[75]World Intellectual Property Organization (1992), pp.75-76.

[76]Ibid., p.85ff.

[77]David Schellhase, in Rosen et al. (2003), p.48.

[78]Rosen et al. (2003), p.56. GPL supporters argue that a person who downloads code written by a thousand different contributors and uses it in a way that is inconsistent with the licence terms is vulnerable to a potential claim by any of a thousand people for copyright infringement and breach of contract; but whether the courts would hold that an earlier contributor whose contribution had been substantially diluted over time still had standing to sue is not clear.

employed by the Sun Community Licence, so that each new contributor enters into a direct agreement with the original licensor.[79] Whether this approach would erect an undue barrier to self-selection of project participants would be a matter for consultation within the biotechnology research and development community.

Product liability and safety and security concerns A typical biotechnology licence contains a number of warranties, indemnities and limitations of liability.[80] One important matter usually dealt with under these provisions is liability for infringement of third party rights, discussed under the previous heading. The other key issue is product liability.

Biotechnology industry participants face substantial product liability exposure, especially with respect to defective design and failure to warn of risks associated with use and forseeable misuse; in medical biotechnology, especially, liability concerns often influence product development and marketing strategies.[81] As foreshadowed in the previous section, although there is no prohibition in the OSD on the giving of warranties, almost all open source licences state that the licensor gives no warranty in relation to the licensed technology, simply because "people who give their software away cannot afford to indemnify others".[82] Presumably, therefore, an open source biotechnology licence would leave downstream innovators responsible for product safety, not just as a technical licensing matter, but because of the need to sustain incentives to volunteer contributions:

> [I]t's very important [from a community perspective] that the person using or developing the final product... is the person who bears all of the responsibility. ... Perhaps that would deter some [follow-on innovation], but the more important thing is to make sure that people who pass on information for free to other people do not have to bear a liability load because if they do, that would stop it dead. ... [P]eople who want to be protected really should be paying for a service contract or for insurance: if you want protection, that's an extra priced service.[83]

The absence of warranties and indemnities in an open source licence (in software or biotechnology) may not be a significant disadvantage in practice for several reasons. First, a disclaimer in a licence agreement does not provide protection from liability imposed by other laws (for example, the Australian Trade Practices Act makes suppliers of open source software liable for misleading and deceptive conduct despite the absence of any warranty in the licence agreement).[84] Second, disclaimers of liability are not peculiar to open source licences: many conventional licences in both fields incorporate such a provision (for example,

[79]Bill Lard in Rosen et al. (2003), p.57.
[80]World Intellectual Property Organization (1992), p.85ff.
[81]Ibid.
[82]Bruce Perens, personal communication.
[83]Ibid.
[84]*Trade Practices Act 1974* (Cth), s.52.

Microsoft's standard end user licences for most products disclaim any warranty in relation to infringement of third party intellectual property).[85] Finally, indemnities are often not worth very much in any case, both because of uncertain interpretation and because the value of an indemnity is wholly dependent on the financial capacity of the entity that provides it.[86]

The relevance of product liability issues to self-selection of licensees under an open source biotechnology licence is that throwing open the technology development process to anyone who wishes to participate would presumably increase the risk of harm resulting from application of the licensed technology. We have seen that this need not be an obstacle to open source biotechnology licensing from a licensor's point of view. However, it may be of concern from a societal perspective. A full discussion of the potential risks and benefits associated with biotechnology research and development is beyond the scope of this thesis; the following brief observations are made in response to concerns about the impact of lowering the barriers to participation under an open source approach expressed by people with whom I spoke in the course of my research.

Two types of problem were anticipated in these discussions. The first relates to biosecurity. In a recent paper titled "On response to biological attack",[87] Roger Brent observes that ongoing developments in biological science and technology facilitate the creation of new biological weapons that go beyond the established pattern of germ warfare – which requires resources and activities of a scale only likely to be feasible for a nation-state or substantially funded organisation – to new threats that require far less skill, capital and effort and may therefore fall within the capability of small groups or even individuals. The question arises whether an open source approach to biotechnology research and development would accelerate the growth of existing threats to biosecurity.

In the software context, the debate over whether releasing software source code poses a security risk for users of that software encompasses two opposing philosophies. The first, sometimes described as "security by secrecy", is based on the argument that disclosure of technical information would benefit hackers (crackers) and create more opportunity for virus attacks.[88] Unsurprisingly, this philosophy is often expounded by proprietary software firms with a commercial interest in maintaining the secrecy of source code. By analogy with this argument, an open source regime in biotechnology would directly increase the risk of bioterrorism by promoting broad disclosure of information about biological systems that could be deliberately used for illegal purposes. As Brent points out, security by secrecy is no longer a realistic option in biotechnology because much of the relevant information is already publicly available; and of course, any technology that is patented is subject to enabling disclosure requirements. The alternative philosophy may be described as "security through openness". Proponents of this philosophy in the software arena argue that under a closed systems ap-

[85] Webbink (2003), p.9.
[86] James (2003), pp.80-81.
[87] Provided to attendees of the Open Source Biology workshop.
[88] Caelli (2003), p.102.

proach, end users are unable to repair the system after a successful attack and have no ability to judge the security status of the underlying operating system or hardware;[89] an open approach has the advantage that users can adapt the technology to their own security needs and need not rely on the security systems put in place by the vendor of the technology.[90] By analogy, security through openness in biotechnology would mean allowing the scientific community at large to keep abreast of technical developments that have the potential to be used for malicious purposes so that if new biological weapons do arise, law-abiding scientists have the capacity to respond (for example, by developing a vaccine against a deliberately released engineered pathogen).

The second type of problem relates to biosafety (both human and environmental aspects).[91] Opponents of genetic modification highlight dangers arising from the disparity between scientists' ability to manipulate biological systems and their ability to predict the results of such manipulation. Increasing the number of practitioners of these techniques through open source-style licensing would presumably increase the potential for adverse consequences due to error or negligence. On the other hand, one attractive aspect of open source biotechnology is that scientific understanding might be improved and the risks reduced by more open scientific exchange and more rigorous peer review under an open source regime. Even though this is probably a better argument in favour of open source biotechnology than the closely related "security through openness" argument, scientists are generally not best placed to make it because, as a group, they have painted themselves into a corner with extravagant promises, made in pursuit of funding dollars, about the benefits of biotechnology research and development – a position that would be undermined by the admission that the scientific foundations of the technology are still shaky.

Ultimately, however, the best answer to the argument that an open source approach to biotechnology licensing would increase biosecurity and biosafety risks is that the appropriate way to deal with these risks is directly, through adequately enforced regulation of potentially dangerous activities, rather than indirectly, through proprietary barriers to entry. This is not to suggest that the regulatory challenges are trivial. On the biosecurity side, illegal use of genetic engineering technology is extremely difficult to detect; it cannot even be assumed that a

[89]Caelli (2003), p 104.

[90]The strength of the security through openness approach is also demonstrated by the attitude of insurance companies, which reportedly charge clients five to fifteen percent more to insure against "hacking" incidents when MS Windows NT software is employed in Internet operations compared with Unix or GNU/Linux: Fitzgerald & Bassett (2003), p.19.

[91]The most interesting aspect of my discussions with informants on this topic was the widespread preoccupation with biosecurity issues – such as the engineering of new biological weapons – to the exclusion of biosafety and broader environmental issues associated with genetic engineering. No doubt this preoccupation was partly due to the timing of my fieldwork, which coincided with the United States' invasion of Iraq in early 2003, and its primary location in the United States, where consumers have historically been far less suspicious of the use of genetic engineering technologies in agriculture and food production than consumers in some other countries (see chapter 1).

biological attack would be readily identifiable as such. On the biosafety side, national regulations governing contained experimentation are expensive and sometimes ineffective, and once genetically modified organisms are released into the environment, the complexity of living systems means the effects are literally impossible to predict or control. Existing liability regimes (developed in response to claims for personal injury, property damage or financial loss) are not well suited to providing redress for any harm associated with such a release because adverse effects may become apparent only over a long period and can be expected often to be diffuse in nature; establishing proof of cause and the nature and extent of any damage would therefore be unusually difficult and expensive.[92] However, relying on de facto controls imposed by intellectual property owners in the pursuit of private profits is no substitute for proper risk management that takes broader social goals into account. As described in this thesis, a shift towards open source biotechnology is not likely to lead to a sudden drastic increase in risky activities, but can be expected to take place more gradually (see chapter 7). While regulators should certainly take note of any such developments and make appropriate adjustments, there is no reason to suppose a smooth transition would not be feasible.

5.4.3 Access in the "preferred form for modification"

Under the OSD, an open source licence must require the distribution of source code with every executable (binary) version of the software (also known as running code). As we saw in chapter 4 (section 4.4.1, p.79), source code is that information which is necessary for modification or repair of a software program; thus, the requirement to make source code available is a necessary precondition to the exercise of other freedoms granted by an open source licence. Licensors are obliged to distribute or otherwise make this information available at no more than the cost of reproduction whenever the program itself is made available, but the OSD does not require the imposition of an obligation to provide source code on licensees who merely copy or modify the program for their own use. The source code must be in the preferred form for making modifications and includes all available documentation describing how to access and modify the original work.

What is the functional equivalent of source code in a biotechnology context?

Clearly, in order to translate open source licensing principles into the biotechnology context, it is necessary to identify the functional equivalent of source code. In general terms, the source code simply represents the wherewithal to understand and make changes to the technology. Exactly what this means in biotechnology licensing depends on the nature of the biotechnology in question; however, ex-

[92] See generally Royal Commission on Genetic Modification (2001), chapter 12.

isting practice in relation to material transfer agreements provides a useful reference.

In addition to defining the terms of transfer of the biological material itself, a typical biotechnology MTA includes a technical description of the material sufficient to enable the recipient to use it (and thereby practise the technology) without having to invest substantial further effort and resources. (As von Gavel observes, "an eppendorf tube with a label 'vector X – gene Y' is pretty useless without at least a vector or plasmid map".)[93] An annex to the agreement often sets out exactly how any material to be transferred is to be described; the description is then transferred with the material itself. This technical description is roughly equivalent to source code, while the biological material itself (in usable form, whatever other conditions this may imply) is like running code.

It is important to realise that the technologically relevant information contained in biological materials – even, to hearken back to Hilgartner's "data stream" model, those that are neither novel nor scarce and are generally accepted as reliable and valuable – is highly uncodified compared with computer software. To take a robust example, consider DNA sequence information. DNA sequence information is often likened to software code; compared with other kinds of biological information, it is indeed highly codified. Yet substantial extra information is required to make sense of a DNA sequence. As one of the leaders of the human genome project has observed, "the raw, unannotated genome is not a usable tool in the hands of the average biologist. ...[P]roviding an analysis [is] essential... to give users the best possible view of the data".[94] A sample annex to an MTA relating to sequence information illustrates the point:

> Provide the following information in electronic format
>
> 1. Name of sequence (plus accession number if available)
> 2. Sequence length
> 3. DNA Sequence – in FASTA format (include ">" and indicate start and stop codon with underline)
> 4. Protein sequence – in one letter code
> 5. Organism of origin
> 6. How sequence obtained – eg Two Hybrid, Sequencing, Database
> 7. Nature of sequence – please stipulate if it is a genomic sequence, a predicted cDNA, or a reverse-transcribed mRNA (real cDNA); full length or partial (if partial provide also predicted full length); what motifs are present and where; what and where are the exons.
> 8. Homology anlaysis – alignments, BLAST search results (only if can do securely) indicating date of search and databases searched.[95]

[93]von Gavel (2001), p.8.
[94]Sulston & Ferry (2002), p.207.
[95]von Gavel (2001), pp.10-11.

Sequence information that is embodied in an actual DNA molecule is stickier still:

> The sequence of the gene/promoter shall be delivered physically in a small-size plasmid (of the "pUC" or "pGEM" type or similar) from which it can be easily isolated using standard restriction digestion. The DNA shall be delivered as a pure plasmid preparation either in a solution or lyophilised, with concentration or amount known and indicated, the minimal amount being 10micrograms of plasmid DNA. Provide also the bacterial strain (indicating details) transformed with the plasmid. Plasmid map shall be delivered in an electronic format (a file on a disc) compatible with VectorNTI (Informax) software and a description of the cloning strategy used to obtain the plasmid with the sequence shall be delivered. [96]

Continuing with the same example, the equivalence between source code and the technical description requirements of a typical MTA was confirmed in less technical terms by a biological engineer seeking to start up a prototype open source biology project:

> [When a genetically modified organism is released], it is no longer private, it is public. At this point by an open source model the owner should be obliged to release the sequence information and also... comments on the code: what it is, what it is supposed to do, what it was designed for, how it is supposed to work. So that somebody else could get up to speed on it quickly.[97]

One way to interpret the need for this extra information is to say that the DNA base pair sequence of a given construction is equivalent not to source code, but to assembly code – an easily readable but only dimly comprehensible string of ones and zeros.[98]

Thus, even if the biotechnology in question is a DNA construct – the closest analogue to software code in the biotechnology context – providing the bald DNA sequence would not normally be sufficient to fulfil an OSD-style source code requirement. This illustrates the general point that the information needed to practise a biotechnological invention is more difficult to transfer – more tightly bound to other elements of the data stream – than software source code.

Given the higher cost to biotechnology licensors of providing the full functional equivalent of source code, should open source biotechnology licences require them to do so? If the standard is set too high and the obligation becomes too onerous, potential licensors might be discouraged from making their technology available on open source terms; on the other hand, the easier it is for users

[96]Ibid. von Gavel provides additional examples for different types of biological material, including seeds, antibodies and cell lines.

[97]Drew Endy, personal communication.

[98]Roger Brent, follow-up email to attendees at Open Source Biology workshop, referring to discussions between Drew Endy and Rob Carlson.

to modify the technology, the greater the likelihood that an open source development effort will succeed. An open source biotechnology community would need to find an adaptation of the source code requirement that strikes an appropriate balance.

In fact, similar problems arise in the software context despite the lower transfer costs, and for this reason open source software licences do allow licensors some flexibility regarding the manner in which source code is made available: for example, as we saw in chapter 4 (p.79), under the GPL it is sufficient to distribute the source code only on request and for a limited period (three years), an arrangement the community regards as "reasonable".[99] Note also that the obligation to provide source code in the software context does not extend to codifying information that would not otherwise have been codified, or to generating new information in order to enable others to use the software – even though there may often be an incentive to undertake such activities in order to reap the benefits of making the program freely available (see chapter 6, section 6.3, p.151ff).

> Hope: Suppose there are uncodified aspects of the technique, and you would normally have to show someone how to do it in the lab. How far do people need to go? How much effort and cost do they need to go to in order to provide that information to all possible licensees?
> Rosen: [I]n my definition you're not obliged to write any documentation at all. It's just if you *have* written such documentation and it relates to how to modify the source code, you have to make it available. But nothing obliges you to generate any documentation about a program.
> Hope: And nothing obliges you to run classes on how to do a particular technique in your lab, or whatever? – From a community building perspective you might want to do it, but in terms of the licence, you are not obliged?
> Rosen: No, there's no requirement at all.[100]

Given that some form of property protection is a prerequisite for open source as well as conventional licensing, it has been suggested that for patented biotechnologies, and perhaps for others as well, a description of the technology that meets the disclosure requirement under patent law would be a reasonable minimum level of information equivalent to software source code.[101] Unsurprisingly, since the purpose in both cases is to enable users to practise the technology, there are strong parallels between source code-related requirements in OSD-compliant software licences and the patent disclosure requirement: in general terms, a patent specification adequately discloses an invention if it contains a description of the best mode of carrying out the claimed invention that is sufficient

[99]Bruce Perens, personal communication.
[100]Lawrence Rosen, personal communication.
[101]Bruce Perens, personal communication.

to enable any person skilled in the art to which the invention pertains to make and use the invention. (It is not necessary that the enablement be such that a person attempting to make or use the invention be successful on the first try; some experimentation may be necessary, but the amount of experimentation required must not be unduly extensive.)[102]

How would an obligation to provide the source code equivalent be triggered?

Recall that in open source software there is no obligation to release source code unless one is distributing copies of the program; private copying and modification of a software program does not incur this obligation. What, then, would be the equivalent of distributing a software program for the purposes of triggering the source code-equivalent obligation in biotechnology?

One view is that a technology should be deemed to have been distributed if either a working version of the technology – the equivalent of running code – or the source code equivalent is made publicly available, intentionally or otherwise. For example, if a genetically modified organism were found to have contaminated a neighbouring field or public land it would be deemed to have been distributed and the intellectual property owner would be obliged to provide all the information necessary for independent scientists to study and modify the organism.[103] On this view, distribution would have a similar meaning to the concept of an environmental release in the context of biosafety regulation. This suggestion is not much more than a starting point for discussion, however: there is room for a range of different approaches within the environmental release paradigm, and the notion of making a technology "public" is, as sociologists of science have shown, highly problematic.

5.4.4 The right to modify the licensed technology

In biotechnology generally, much more than in other technology contexts – with the possible exception of software development – it is common for the parties to a licence agreement to make improvements to the technology during the licence term.

As we saw in chapter 4 (p.81ff), to comply with the OSD, a licence must allow the creation of modifications and derived works and must allow them to be redistributed under the terms of the original licence.

The purpose of this requirement is to make sure the technology can evolve freely by preventing the owner from obstructing either changes to the technology or the spread of changes. Without such a licence provision, the owner would be able to block the evolution of the technology. This is because under copyright law,

[102]Eric G. Wright, Disclosure, Modern Drug Discovery October 2000 Vol. 3, No. 8, p. 69, at http://pubs.acs.org/subscribe/journals/mdd/v03/i08/html/10patents.html, citing relevant statutes and case law. The OSD specifies that the source code be in the preferred form for modification of the technology and that deliberate obfuscation is unacceptable (see chapter 4, p.79).

[103]Drew Endy, personal communication.

as we saw in chapter 4, the permission of the copyright owner is needed in order to prepare or authorise the preparation of derivative works or to copy, modify or distribute the derivative work as a whole (although copyright in a derivative work is held by the author of the derivative work, this copyright covers only the additions, changes, or other new material appearing for the first time in the work and does not extend to any pre-existing material).

We saw earlier that biotechnology-related innovations may be protected under patent or plant variety laws or as trade secrets or personal property. The scope of the exclusive rights granted to the intellectual property owner is different under each of these regimes, but all give the owner some degree of power to block the development and dissemination of improvements on the technology.

As an example, consider the relationship between first or "basic" and subsequent "improvement" patents.[104] (In the technical patent context, the word "improvement" generally means technology that builds directly on a prior patent. In a broader sense, an improvement may be considered to be something that modifies portions of the technology of the prior patent, as distinct from merely providing an alternate approach to achieving the same result.)

In patent law, the holder of an improvement patent is the owner of a separate invention from that protected by the prior patent. However, obtaining a patent does not of itself give the right to practise the patented invention: a patent only grants the patent owner a negative right (i.e., the right to prevent others from making, using, or selling the patented invention). In many instances, a patented improvement cannot be made, used, or sold without infringing the prior patent (to determine whether the improvement patent can be practised without infringing the basic patent, the claims of the prior patent are compared with the improvements).

For example, suppose a patent is obtained for seed A. Another person decides that the seed would be more useful if it had an added gene B and obtains a patent for seed A with gene B. The improvement patent would give the owner the right to keep others from making, using, or selling seed A with gene B. As the original patent claimed seed A, making, using, or selling seed A with gene B would infringe the basic patent. The presence of the additional gene permits the inventor of the improvement to obtain a patent, but does not avoid infringement of the basic patent for the seed.

Similarly, with regard to biological materials, recall that such materials are bailed goods, and that the definition of bailment includes an obligation for the goods to be re-delivered in either their original or altered form, as soon as the time for, use for, or condition on, which they were bailed has elapsed or been performed. Thus, a provider of biological materials has the ability to control the creation and dissemination of any modifications or improvements to the original material, limited only by what the recipient is prepared to agree to under the terms of the bailment agreement.

These examples show that an open source biotechnology licence, like an open

[104]This discussion is based on Silverman (1995).

source software licence, would need to make explicit provision to ensure the freedom to make and distribute modifications and improvements. To what extent does a typical conventional biotechnology patent licence or MTA already do this?

With respect to patented technology, in conventional biotechnology licensing, a licensor will usually seek the right to use any improvements to a patented technology made by a licensee.[105] A licensor may be tempted to seek an exclusive licence or outright assignment of any improvements made by the licensee, but provisions of this type generally offend against competition rules and are likely to be unenforceable.[106] It is, however, quite common for the licensor to be given a non-exclusive, royalty-free licence to use licensee improvements, often together with the right to sublicense the improvement to other licensees of the same technology.[107] This arrangement is discussed further below in relation to translating copyleft-style provisions into the biotechnology context (section 5.4.4, p.128.).

With respect to biological materials, a typical MTA attempts to deal with the difficulty of defining improvements and other changes to commonly transferred materials such as DNA, RNA, proteins, cells and organisms by creating a series of categories. (This is a good example of the law's "atomistic" approach to defining rights in evolving data streams; in the case of living materials, the data stream is capable of evolving independently of human intervention: see the description in chapter 2 of data streams as chains of products, p.14.) These categories and the usual terms applying to each are as follows.[108]

The provider owns the actual biological material transferred (the "original material": say, a gene X), any unmodified descendant of original material ("progeny": in this example, copies of gene X obtained by polymerase chain reaction) and any unmodified subset of the original material ("unmodified derivatives": protein X, produced by translation of gene X). The recipient cannot distribute these to a third party.

The recipient owns any humanly altered form of the original material that incorporates the original material in part or as a whole ("modifications": for example, a genetically modified plant or a vector incorporating gene X) that he or she might generate. Typically the terms of the MTA will provide that the recipient can distribute them to a third party, but only with written permission of the provider. Often the provider must be given an option to take an exclusive licence on any modifications, though this is not generally a royalty-free licence.

The recipient owns any other substances that he or she obtains through the use of the material (that are not modifications, progeny or unmodified material: to continue the same example, this might be a protein Y that interacts with protein X or a gene Z that codes a receptor for protein X), and can distribute them to others, again only with the permission of the provider of the original material. In

[105]World Intellectual Property Organization (1992), p.72.

[106]Ibid.

[107]Ibid., p.73.

[108]World Intellectual Property Organization (1992), pp.76-81; von Gavel (2001), pp.8-13, citing Barry Datlof and the UBMTA (above, p.100), available at http://www.autm.net/UBMTA/master.html, last accessed 25 October 2004.

the case of other substances that are classified as tools, the licence will not usually require the licensee to give the provider of original materials an option to take out an exclusive new licence. However, in the case of other substances that are classified as technologies, templates or new uses it is common for the provider of the original material to be given an option for an exclusive new licence. Again, this is not generally a royalty-free licence.

In summary, the licensor owns the original material and any progeny and unmodified derivatives, while the inventor (whether licensee or licensor) owns modifications plus any substances obtained through the use of the material, not including any part of those substances which are themselves original material, progeny or unmodified derivatives. (Note that the concept of derivatives in biotechnology is not related to the concept of derivative works in copyright law.)

These arrangements differ substantially from an open source-style MTA, in which the provider of biological materials would not impose any restrictions on distribution of original materials, progeny, unmodified derivatives, modifications or other substances obtained through the use of the material. No permission would be required for distribution to a third party, and the provider would not be given the option of an exclusive licence on modifications or other substances. (It would not necessarily be inconsistent with an open source-style MTA for the recipient of biological materials to be able to charge royalties on the use of modifications and other substances by the original provider or by third parties, unless the original MTA was expressed as a copyleft-style agreement: see next section.)

Copyleft: preserving ongoing access to an evolving technology

We saw in chapter 4 that not all approved open source software licences incorporate the copyleft mechanism, but that by far the most often used open source licence is the GPL – the archetypal copyleft licence. A similar preference would be likely among users of open source biotechnology licences, reinforced by cost considerations.

As we saw earlier (p.115), obtaining patent protection requires substantial resources (in the order of thousands to tens of thousands of dollars), whereas copyright is automatic and cost-free (for a discussion of simple publication in the biotechnology context, see below, section 5.4.4, p.135). Similarly, maintaining patent protection entails the payment of substantial yearly fees, while litigation to enforce patent rights or defend against challenges to patent validity is notoriously complex and expensive.[109]

It is often assumed that these higher costs would be an obstacle to implementing open source licensing principles in biotechnology because, in a typical biotechnology licence, maintenance and enforcement costs are partially recovered from the licensee through royalty payments, which are precluded by the free redistribution requirement of the OSD. However, this reasoning is based on a misunderstanding. In a conventional biotechnology setting, both parties have an in-

[109] Above, note 69.

terest in maintaining the licensed rights and pursuing anyone who uses the technology without obtaining a licence or in breach of the licence terms because both parties want to exclude free riders. (In open source the parties also have a mutual interest in enforcement, in this case to guard against excessive defection from the co-operative effort that would diminish everyone's incentive to participate.) It is therefore common for licensor and licensee to share in the costs of patent enforcement and to notify each other of infringements by third parties.[110] To the extent that the responsibility of maintaining and enforcing patents is shared between licensors and licensees, provision for these costs in the remuneration clauses of the licence does not represent a real transfer of funds, but is merely an administrative convenience to allow maintenance and enforcement tasks to be carried out on behalf of both parties in the most efficient way.

Thus, the real cost issue is not related directly to licence remuneration, but to the overall wealth of the parties and whether they can fundamentally afford the costs of playing the patent game. It might be thought that technology developers who do not seek to recover licensing revenue from users would have fewer resources than those who adopt a conventional approach to intellectual property management, and might therefore be unable to maintain the strong patent position that would be needed for an effective open source strategy. As we saw in the discussion of open source as a business strategy in chapter 4 (p.75), the assumption that an open source strategy always brings lower returns than conventional exploitation strategies is unsound (we return to this issue in the next two chapters). However, the higher cost of patent protection relative to copyright protection does mean that a non-copyleft open source approach (see section 4.2.3, p.71) would be unlikely to be cost-effective in many situations. An example of a non-copyleft open source licence is the BSD licence, which imposes an obligation on licensees to acknowledge the work of the original author but otherwise allows the licensee the same freedoms as if the code were not subject to copyright. A copyleft approach offers greater economic benefits than a restriction of this kind, which is presumably not valuable enough by itself to justify the cost of patenting – though it might be used where a patent has already been obtained for other reasons or in support of a "sell it, free it" business strategy (see chapter 7, section 7.2.2, p.212.).

A method of rewarding contributions based on ongoing access to an evolving technology appears to make good sense in at least some biotechnology contexts. For example, a major problem in negotiating arrangements for benefit-sharing in regard to plant germplasm used for food and agriculture is that, while it is clearly unethical to disregard the contributions made by many farmers over many generations, especially in developing countries, the economics of tracking these contributions and determining the value of each may not be feasible.[111] A standard

[110]World Intellectual Property Organization (1992), p.92.

[111]John Barton, personal communication. Tracking ownership and negotiating and administering remuneration clauses are two of the most complex and therefore the highest transaction cost aspects of conventional biotechnology licensing, even for technologies with only a few easily identified contributors: World Intellectual Property Organization (1992), pp.74-76.

material transfer agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture could incorporate open source-style terms that would make access to the evolving technology the usual reward for contributions rather than direct remuneration through royalties or similar payments.[112] The agricultural germplasm case is an extreme example of a common phenomenon in biotechnology: due to the cumulative nature of most technologies and their origins in publicly funded academic research, the pedigree of a technology when it is first commercialised is often not fully known. A copyleft-like mechanism in biotechnology would sidestep the need to place a money value on contributions to cumulatively developed technologies; by creating an alternative form of compensation, it would remove a major source of uncertainty and high transaction costs. Such a mechanism would also help to overcome problems of trust in forming collaborations among diverse institutions in biotechnology.

Thus, in order to demonstrate the practical feasibility of open source biotechnology licensing, it would be necessary to show that the copyleft mechanism described in chapter 4 could be adequately translated into biotechnology. What would this entail?

Is a biotechnology version of copyleft broadly feasible? As with the OSD requirement to provide source code when distributing an open source software program, the first step in translating copyleft into the biotechnology context is to describe the concept in functional terms. Although those who see copyleft as a unilateral copyright permission rather than a contract would regard any operation of copyleft outside the copyright environment as "a metaphor rather than a legal rule",[113], there is nothing inherent in the concept that ties it to a particular proprietary regime. As General Counsel for the Open Source Initiative has remarked, "you don't need a big philosophy about copyleft, and you don't need a new word for it: it's just about reciprocity." [114] In particular, recall from chapter 4 (section 4.2.2, p.68) that the distinctive feature of a copyleft licence is that it is conditional upon the licensee distributing any improvements to the licensed technology on the same terms as those of the original licence.

In the previous section, we saw that non-exclusive grant-backs of licensee im-

[112]International Treaty on Plant Genetic Resources for Food and Agriculture (Rome, 3 November 2001) [2002] ATNIF 14 (entered into force 29 June 2004) (PGRFA). Article 12.4 provides for facilitated access to plant genetic resources for food and agriculture within the Multilateral System established under article 10, pursuant to a standard material transfer agreement (MTA) to be adopted by the Governing Body. The terms of the standard MTA, which are to be in accordance with conditions set out in Article 12.3, are still under negotiation: at Rome on 15-19 November 2004, the Second Meeting of the Food and Agriculture Organization Commission on Genetic Resources for Food and Agriculture (acting as the PGRFA Interim Committee), received a report on the outcome of the Expert Group on the Terms of the Standard Material Transfer Agreement, available at http://www.fao.org/ag/cgrfa/docsic2.htm, last accessed 22 December 2004. (The official English version of the PGRFA is available at ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf, last accessed 22 December 2004.

[113]Eben Moglen, personal communication.

[114]Lawrence Rosen, personal communication.

provements are well known in conventional biotechnology licensing. Such terms are commonly used to establish a limited innovative network in the following way. The original licence is non-exclusive; each licensee grants the licensor a non-exclusive, royalty-free right in any improvement developed by the licensee, together with the right to sublicense the improvement to other licensees of the same technology. The licensor circulates such improvements among all licensees on a royalty-free basis, with ownership in each improvement being retained by the party developing the technology. Such networks have been described as generating a "club atmosphere" that encourages cross-fertilisation of improvements among licensor and licensees so that the basic technology can continue to provide commercial advantage from which all parties benefit.[115]

This type of arrangement is very similar to that established by copyleft licensing, and has essentially the same rationale: both are a means of facilitating "collective invention" (see chapter 6, section 6.4). From a licensing perspective, there are two key differences between a biotechnology "club" in which members are obliged to grant back improvement rights and a copyleft-based open source development project. First, as we saw earlier in this chapter, in the copyleft setting there is no limit on club membership. Not only can the licensor keep expanding the number of licensees, but every licensee has full sublicensing rights, as does every sublicensee, and so on. At the same time, any person who obtains a working version of the technology is entitled to a licence. Second, in the copyleft context the licensor has no special role in co-ordinating the circulation of improvements; instead of granting rights in any improvements to the licensor alone, the licensees agree to grant such rights to all comers, so that (at least so far as the transfer of legal rights is concerned) dissemination of improvement technologies is decentralised – similar to messages that are broadcast rather than routed through a telephone exchange. This is regarded as an important element of the open source approach: Lawrence Rosen has remarked that "the only way open source meaningfully works is if you can encourage people to create and use without having to go back to you for permission".[116]

It is clear from this functional description that copyleft may be characterised as an unusual form of reach-through licence agreement, in which the price extracted by an initial innovator for allowing the technology to be used to create follow-on innovations is not a royalty payment but a guarantee of continuing access to the technology as it evolves – not only for the initial innovator but for anyone who can use it. Eben Moglen, author of the GPL, describes copyleft as a way of using "the exclusive powers of one set of people... to create a hook for giving other people access to a commons from which they can't withdraw".[117] Whether or not this would prove an attractive option for biotechnology licensors, given the familiarity of patent lawyers with reach-through provisions designed for other purposes, there appears no legal reason why this type of reach-through

[115]World Intellectual Property Organization (1992), p.73.
[116]Lawrence Rosen, personal communication.
[117]Eben Moglen, personal communication.

agreement could not be incorporated into a patent licence or other type of contract in the biotechnology context.

Of course, biotechnology reach-through licence agreements have at various times been subject to heavy criticism. Reach-through agreements are one of the pathways to anticommons tragedy described by Heller and Eisenberg (chapter 3, p.35) because they give initial innovators a continuing "seat at the bargaining table" in relation to downstream innovations.[118] Some of the costs associated with stacking licences would be relevant to a biotechnology version of copyleft – for example, those mentioned earlier regarding the difficulty of tracing the technology's pedigree – but in general the transaction costs would be substantially lower than those associated with proprietary reach-through agreements because the nature of the reach-through condition is to mandate licensing terms that are inherently less costly than the conventional approach (above, section 5.4.1, p.106).

In addition to the problem of co-ordinating multiple ownership rights in a cumulative technology, reach-through patent licences have sometimes been regarded as a form of patent misuse. Exclusive grant-backs by way of assignment of ownership to the licensor may be considered a violation of competition laws where the licensee is forced to agree to such conditions in order to gain a licence to use the patented technology.[119] However, this is less likely where the grant-back is non-exclusive and the party that developed the technology retains full rights. According to the World Intellectual Property Organisation, the non-exclusive "club" arrangement described above does not amount to patent misuse in any major industrial country;[120] by analogy, it is unlikely that a copyleft-style patent licence would come into conflict with competition laws.

The other obvious issue raised by the description of copyleft as an unusual form of reach-through agreement relates to the fact that the licensee promises to make improvements available not just to the licensor but to all comers. Under the doctrine of privity, as a general rule, even though a contract may benefit a third party, only a person who is a party to the contract can sue on it. This creates a problem of enforcement, which, however, could be solved in practice by the assignment of rights to a central enforcement agency (see below, section 5.4.4, p.140).

Specific issues to be addressed in drafting a working copyleft-style biotechnology licence In principle, then, it would be possible to draft a copyleft-style agreement to apply in the biotechnology context. The next question is what such an agreement might look like. The following discussion is not intended to be prescriptive, but merely to articulate some of the issues that might need to be addressed in drafting a working licence.

[118]Heller & Eisenberg (1998).
[119]World Intellectual Property Organization (1992), p.73.
[120]Ibid.

Defining the equivalent of copyright "derived works" In devising the specific terms of a copyleft-style grant-back in the biotechnology context it would be necessary to strike an appropriate balance between incentives to contribute based on the promise of continuing access to the evolving technology and licensees' freedom to undertake innovative activity for proprietary purposes in the same technology area. The part of the licence that would set the balance of incentives would be the definition of the equivalent of a "derived work" (referred to so far in this discussion as an improvement). The function of a copyleft licence as a means of facilitating co-operative technology development suggests that the net for catching improvements to be kept within the common pool should be cast widely:

> Your definition of [the equivalent of] a derived work should be quite broad. If too many people are able to take advantage outside the expected terms of the licence – in other words people are putting their software out there expecting share and share alike as with the GPL – and people circumvent that quid pro quo, that tends to make your community walk off and do something else, and so you need to be careful that not too much of that happens.[121]

The same reasoning suggests that effective enforcement would be an important aspect of open source biotechnology licensing. Some practical enforcement issues are canvassed briefly below, but one factor that would directly affect the ease of enforcement is the degree of certainty that could be achieved with respect to the above definition. In the software context, the defintion of derived works taps into an established (though, as we saw in chapter 4, somewhat confusing) body of law that gives the parties a shared reference point in interpreting the terms of the licence. Ideally, an open source biotechnology licence would also draw on established legal terminology. As we saw in our discussion of standard MTA provisions, there do exist some relevant terms in the biotechnology context whose meanings are comparatively stable and well understood. However, choosing exactly the right terminology would require careful consideration. To illustrate the point, the difficulty of precisely defining in an MTA what constitutes a "derivative" of a given biological material is well recognised, and empirical evidence suggests that lawyers and scientists define the term very differently: lawyers tend to define it broadly, as including anything at all that is produced using the original material, whereas scientists tend to adopt a more narrow definition based on scientific criteria.[122]

It has been suggested by the author of the GPL that the degree of certainty that could be achieved in defining which modifications should be subject to a copyleft-style grant-back obligation would be adversely affected in biotechnology by the comparatively loose fit between the technology itself and the relevant

[121] Bruce Perens, personal communication.

[122] Kathy Ku, personal communication.

property rights.[123] The essence of this argument appears to be that in software, copyright subsists in the object code, itself a functioning technology, whereas in biotechnology, the scope of intellectual property protection is defined by a written *description* of the technology (the patent claims) which is necessarily open to interpretation:

> Copyright just says, "Here's my expression, take it as it is". The patent system says, "Here's how I have done what I have done"... . The claims are what the system protects. So that process of mapping into claims is the primary source of the difficulty. What we really want is for people to say "Here's a thing, I put it in commons; it is what it is, it's self-describing. Use it for whatever you want, but whatever you make of it, put it back in the commons."[124]

The implication seems to be that there would inevitably be greater uncertainty about the conditions of access to a biotechnology commons than about the conditions established by copyleft terms in the software context. It is further suggested that this difference in the relationship between technology and property rights in software and biotechnology means that direct translation of copyleft obligations into the patent context would create an inappropriate balance of incentives for potential users. The reasoning is that copyright in software code cannot be infringed except by copying, modifying or distributing the code, whereas patent rights in biotechnology inventions can be infringed by actions that do not relate directly to the technology itself, so a "patent-left" grant-back condition would be more restrictive than the copyleft grant-back; on the other hand, limitations on patentability would mean some technologies or elements of technologies would not be caught by a copyleft-style patent licence:

> The control the patent system offers you isn't the right amount. It controls against independent reinvention, [and] you've got the doctrine of equivalents... .[125] [By contrast,] copyrighted works aren't ousting anybody. You can say "Look at my work, then go and invent it yourself, that's fine". But patents are a little stronger. At the same time the patent system also in some sense locks up too little because of the limits on patentable subject matter. So [the] gateways in and out [of the commons] won't be perfectly shaped; it's going to leak in ways that we wouldn't like and it may exclude some things that we would like to have.[126]

[123]This paragraph and the next reflect my understanding, possibly flawed, of points made in conversation by Eben Moglen.

[124]Eben Moglen, personal communication.

[125]Under the doctrine of equivalents, courts will find infringement where none literally exists. If the allegedly infringing device or method is sufficiently similar, even if it is not identical to that defined by the claims, then courts will consider it infringing because it is equivalent to the claimed invention.

[126]Eben Moglen, personal communication.

(Another respect in which the patent system may be regarded as "locking up too little" relates to the term of protection: the enormous discrepancy between typical product life and the duration of intellectual property protection in the software case means that the access provided by a copyleft licence is effectively indefinite. This would not be true of many patented biotechnologies, despite patent "evergreening".[127])

These observations illustrate the speculative quality of current thinking about how a copyleft-style biotechnology licence might work. However, conceptually they may not advance the discussion very far. To begin with, copyright in software code is not tied directly to its functionality, but subsists only in those elements of a program that contain the author's original expression. In theory, the copyrightable elements of software code are identified by a process of abstraction, filtration and comparison,[128] but in practice this process is unwieldy and its outcome uncertain.[129] Even if copyrightable expression and functional code really were one and the same thing, it is not clear why a comparison between copyright and patent rights as the means of establishing a technology commons would be relevant in the biotechnology context. In software, the outcome of such a comparison might add fuel to arguments against the desirability of granting software patents, but for the present purpose the relevant comparison is between the "patent-left" approach and other options open to innovators in the biotechnology context for disseminating a new technology. One such option is to refrain from seeking intellectual property protection altogether, instead relying on "a good publication that says 'Here it is!'".[130] This approach can be dangerous in a proprietary environment, in that simple publication is not always sufficient to defeat a subsequent patent claim, but in any case, it leaves the innovator without any leverage by which to gain access to later technologies developed using his or her input. The other option is to obtain intellectual property protection and adopt a conventional proprietary approach to exploitation. In either case, the innovator will still be affected by any uncertainty inherent in the patent system. Similarly, the area covered by a patent holder's exclusive right is the same no matter how that right is exploited; the fact that patent scope may be wider in some respects and narrower in others than copyright has no bearing on the decision whether to adopt a conventional or "patent-left" approach in biotechnology.

Acknowledging the limits of ownership Nevertheless, the preceding discussion highlights an important point: you cannot use property rights to control what you do not own. As we saw earlier in this chapter (p.96), the conventional

[127]Patent owners employ a range of strategies to extend effective patent life; a common approach is to obtain separate twenty year patents on multiple attributes of a single product. See, for example, European Generic Medicines Association, "Evergreening of Pharmaceutical Market Protection", http://www.egagenerics.com/gen-evergrn.htm, last accessed 22 December 2004.

[128]*Computer Associates International* v. *Altai* 982 F.2d 693, 23 USPQ2d 1241 (2d Cir. 1992); *Feist Publications, Inc.* v. *Rural Telephone Services Co.*, 499 U.S. 340 (1991).

[129]Hollaar (2002), section IIIB: "Abstraction, Filtration, Comparison".

[130]Lita Nelsen, personal communication.

approach to exploiting biotechnology-related innovations involves restricting access to the technology using a combination of intellectual property rights, personal property rights and trade secrets. Trade secrets are useful where the goal is to maintain overall exclusivity, but unlike true property rights used as copyleft "hooks", they are not so useful in achieving the opposite goal because they do not survive disclosure outside a confidential relationship.

An example from open hardware illustrates the point.[131] The Simputer Trust is a non-profit group of Indian scientists and engineers who have developed a handheld, simple-to-use computer – the "Simputer" – with the aim of helping poor and illiterate citizens to access information. The Simputer supports software that can read web pages aloud in several native Indian languages and uses Smartcard storage of user preferences to allow the purchase cost, already low, to be shared among many users.[132] The Simputer's system software is covered by the GPL, and the group wanted to license the hardware on similar terms in order to facilitate the spread of the technology and its extensions.

Under the Simputer General Public Licence (SGPL),[133], any individual or company can download the hardware specifications free of charge, but by doing so agrees that any derivative work will come back to the Trust within one year to allow for further dissemination; such improvements are subsumed in the definition of "specifications" and hence governed by the same licence. Lawrence Rosen, General Counsel for the Open Source Intiative, gives the following warning (speaking in general terms and not as a specific comment on the SGPL) about this type of arrangement:

> People try to license a lot more than they have a right to licence [because] they are afraid of the very open source characteristic that they are trying to build. ... [Companies] want their specifications to be under... a GPL-like licence, because whatever improvements are made by others they will be able to capture. But at the same time they want to be able to control those improvements. ... They say: "I'm going to control the specifications. I'm going to let you [develop whatever] you want as long as you do it according to my rules, that everything will stay open." But wait a second – what gave you the right to dictate the rules? ... Certainly if you get someone to agree that if he reads the specification then he will do certain things with respect to [technology] written to that specification, it's a contract and anyone who has signed... a reasonable contract... has some obligation to follow its terms. But what happens if a copy of the specification...

[131]The open hardware movement has its roots in the radical technology movement of the 1960s and the subsequent development of bazaar-style chip manufacture (see chapter 7, p.213), and is currently enjoying a renaissance, partly due to the success of the free and open source software movement and the advent of the Internet: Open Collector, "What is 'Open Source Hardware'?", http://opencollector.org/Whyfree/, last accessed 22 December 2004.

[132]Ward (2001); Simputer Trust (2004).

[133]Available at http://www.simputer.org/simputer/license/sgplv1.3.php, last accessed 22 December 2004.

> finds its way to someone who does not make a copy of it, but simply finds it and starts to read it [and then] without copying the document, which is itself copyright, [builds a technology] to those specifications? He's not bound."[134]

A similar issue might arise in relation to protocols and other technical information distributed with biological materials. As with hardware specifications, these documents may be at least partly protectable under copyright as expressive works, but the ideas they contain cannot be controlled except through confidentiality requirements. The SGPL attempts to solve this problem by requiring users to ensure that "no third party can receive or read the specifications from you without having first read and agreed to the terms of this SGPL".[135] Rosen (as above, speaking in general terms and not as a specific comment on the SGPL):

> Every open source licence I write says "you're entitled to the source code", and the source code, by definition, is all information necessary to modify the program. You can't keep it secret. [So] I don't think that's going to fly in open source. It's a legitimate thing to do, don't get me wrong – you can have confidentiality obligations and other kinds of things. But... it's not the point of open source."[136]

The Simputer Trust's response to emailed criticisms of its licence by GPL enthusiasts is that, "while the philosophy of the Simputer distribution is rooted in the GPL philosophy, where departures from the philosophy are mandated to achieve the social purpose, the model will be appropriately altered."[137] As stated earlier in this chapter, this is a reasonable approach, but in this case the use of non-disclosure agreements creates a potentially formidable enforcement problem.

Enforcement As we saw earlier, a typical biotechnology licence makes provision for maintenance and enforcement of the licensed rights. How would these issues be dealt with in an open source biotechnology setting? Thinking on this issue is also far from advanced:

> If you put restrictions on [your licensees], how are you going to enforce your restrictions? ... Are all the good scientists out there going to watch out for you and report if someone violates the on-licensing restrictions? ... Are you going to have all this come back through a central repository that then handles that enforcement function? Do you even need an enforcement function, or could you just let things go and say you don't care?[138]

[134] Lawrence Rosen, personal communication.
[135] Above, note 133.
[136] Lawrence Rosen, personal communication.
[137] Above, note 133.
[138] Kevin Sweeney, Open Source Biology workshop.

As we saw earlier (p.129), the parties to an open source biotechnology licence would have a mutual interest in intellectual property enforcement, not to prevent the use of the technology by free riders, but to guard against excessive defection from the co-operative effort: in a competitive setting, appropriation of improvements to technologies made freely available under a copyleft-style licence in breach of the licence terms could create real economic disadvantage for those who comply with the terms of the agreement. Also for the sake of maintaining co-operative development, the parties would have a shared interest in defending against challenges to the validity of their patent intellectual property rights.

Common warranties given by the licensee to the licensor in a typical biotechnology licence include an agreement not to challenge the validity of the licensed rights.[139] Challenges by licensees to the validity of intellectual property rights may be less likely to arise in an open source biotechnology context because the licensee is not being charged a substantial sum for access to the technology and his or her immediate use is not being restricted. Walsh et al., in their study of biotechnology industry licensing practices (see section 3.3.2, p.42) found that biotechnology owners tend not to challenge the validity of each other's rights where those rights are freely cross-licensed: rather, threats come from those who are excluded from cross-licensing arrangements.[140] Nevertheless, an open source licensor's intellectual property rights may be challenged by industry participants moving to an end-game strategy. This possibility was canvassed in the conventional biotechnology setting by Walsh et al.,[141] and in fact, these are the circumstances in which enforcement issues have arisen in open source software.[142]

One method that open source software licensors have adopted in response to the threat of litigation is to incorporate mutual defence clauses into some open source software licences. In software as in biotechnology, most patent licences are granted on the condition that the licensee will refrain from suing the licensor for patent infringement; some such provisions have been very broadly worded. The reason is that in software (as in most industries), patents are mainly valued as a defensive weapon because bringing a suit for patent infringement is expensive, cumbersome, and risky. Some open source software licences contain a "mutual defence" provision similar to the agreement not to challenge patent rights found in a typical biotechnology licence, except that it extends to rights under all open source licences, not just the one in dispute, and so is a stronger deterrent:

> The [open source community] got together and said "OK, we can play that game too. ... If you sue the licensor for patent infringement, your licence to any OSI-certified software terminates. We're going to defend each other."[143]

[139]World Intellectual Property Organization (1992), p.76.

[140]Walsh & Cohen (2003), p.329.

[141]Ibid.

[142]Brian Behlendorf, personal communication, referring especially to the current litigation between SCO and IBM (see chapter 4, p.91).

[143]Lawrence Rosen, personal communication.

As we saw earlier (p.115), one practical issue often raised in discussions of the feasibility of open source biotechnology licensing is the high cost of maintaining and enforcing patent protection. Even though the blanket assumption that an open source strategy brings lower returns than conventional exploitation strategies is not justified, most industry participants in an open source biotechnology setting might indeed tend to have fewer resources than most conventional players simply because open source would lower the bar to industry participation. The simple solution to cost problems for poorer open source industry participants would be to contribute to a joint fighting fund or to assign their rights to a central agency (see below, p.140). In addition, small players could expect to benefit from the strength of a few larger players (see chapter 7, section 7.3.3, p.221) who would "go into bat" on behalf of the whole community:

> It isn't worth suing unless a larger company is involved in the infringing activity. If that is the case, the big company will go into battle, effectively defending the smaller players engaged in the same alleged infringement, as with IBM in the SCO case.[144]

In the open source software context, enforcement costs are kept to a minimum by the use of informal methods, such as mediation, which have been very effective in bringing about compliance with licence terms.[145] Much has been made of the importance of community norms in this context,[146], and it has been suggested that no sufficiently tight-knit community exists in the biotechnology context for community norms to play a role in enforcement.[147] However, even if the existence of a normative community does play an important deterrent role in the software context, and even if there is no such community in biotechnology, it does not follow that informal methods would be ineffective. If enough industry participants are linked to each other in a pattern of repeat transactions for non-compliance to carry the risk of generalised reprisals in future negotiations, informal methods of enforcement are likely to be successful.

A number of other difficulties arise with respect to the enforcement of open source licence terms due to the potentially large number of contributors to any given technology. Three practical issues have been noted in the open source software context, relating to standing to sue for copyright infringement, procedural matters and remedies.

Standing to sue in relation to copyright infringement is strictly limited. In software usually only the author of a particular piece of code or his or her exclusive licensee or assignee (for example, an employer if the code is written in the course of employment) has standing.[148] An open source software program generally contains code written by many different authors, none of whom in-

[144]Brian Behlendorf, personal communication.
[145]Webbink (2003), p.9.
[146]See generally O'Mahony (2003).
[147]Opderbeck (2004).
[148]Fitzgerald & Bassett (2003), p.12; Rosen et al. (2003), p.45.

dividually is likely to have the resources necessary for litigation.[149] A common solution in copyright generally is for individual authors to assign their rights to a single organisation that can handle enforcement on behalf of all contributors to a particular technology or on behalf of all contributors to technology licensed in a particular way. This is the method employed by the Free Software Foundation with respect to code covered by the GPL:

> In order to... be able to enforce the GPL most effectively, FSF requires that each author of code incorporated in FSF projects provide a copyright assignment, and, where appropriate, a disclaimer of any work-for-hire ownership claims by the programmer's employer. That way we can be sure that all the code in FSF projects is free code, whose freedom we can most effectively protect, and therefore on which other developers can completely rely.[150]

While there are some disadvantages to this approach in relation to cumulative technologies – in particular, it can be expensive in terms of transaction costs when dealing with existing code – [151], these are not insurmountable, and at the Open Source Biology Workshop in March 2003, the collecting society model emerged as the most promising approach to enforcement. Of course, any open source biotechnology project should establish some efficient way of tracking the ownership of contributions from the beginning. As noted earlier in this chapter, such problems arise in conventional biotechnology licensing also; existing biotechnology licensing initiatives may therefore offer some guidance in this regard.[152]

Procedural issues in open source software enforcement include how to join a large number of copyright owners in an infringement action and how to ensure all owners are served notice of the proceedings.[153] There may be difficulties as to what remedies are appropriate, given different sized contributions and the fact that contributors have not required payment or royalties for their work; the lack of financial compensation for contributions also makes conventional harm and loss difficult to establish. The appropriate remedy for infringement in an open source context would presumably be the equitable remedies of injunction and specific performance (to disclose the source code of any derivative work), together with the threat of having to account for profits.[154] It would be necessary

[149]A mere distributor, such as Red Hat, has no standing; but note that the position of an organisation or individual that co-ordinates the programming efforts and manages the results of a community effort in open source develoment is not so clear: a compilation copyright may be held by the project manager independent of underlying copyrights in individual modules of the program so that that person may have standing to enforce copyright in a compilation. James (2003), pp.83-84.

[150]Free Software Foundation, "Why the FSF gets copyright assignments from contributors", http://www.gnu.org/copyleft/why-assign.html, last accessed 22 December 2004.

[151]O'Mahony (2003); Gampe & Weatherley (2003), p.121.

[152]For example, the PIPRA initiative (section 3.5.4, p.59) will make use of a range of existing Web-based patent search tools: see Graff et al. (2001).

[153]James (2003), pp.83-84.

[154]Fitzgerald & Bassett (2003), p.36; James (2003), pp.83-84.

in establishing an open source biotechnology licensing scheme to consider how patent law remedies would fit with open source objectives.

It should be noted that these practical difficulties relating to enforcement are not so much a property of open source licensing versus conventional proprietary licensing as they are a property of collaborative, bazaar-style development versus in-house, cathedral-style development. As we have seen, collaboration (with associated transaction costs, including those related to enforcement) is already an integral part of biotechnology development; the question is whether an open source or conventional approach to collaboration is likely to be most effective in any given case.

5.5 Conclusion: licensing in biotechnology

In this chapter I have argued that an open source approach to biotechnology research and development is not only desirable, but feasible. The first step in establishing the feasibility of open source biotechnology is to show that open source licensing principles can be applied in a biotechnology context. Taking the OSD as a statement of open source licensing principles, this chapter compared conventional biotechnology licensing practice with the key elements of the OSD, relating to self-selection of licensees and to the practical wherewithal (access to source code equivalent) and legal freedom to make changes to the licensed technology necessary for cumulative development. The results of this comparison indicate that while translating open source principles into biotechnology licensing would raise a number of technical issues, these would not be insurmountable, assuming technical expertise could be made available. The Creative Commons example (section 3.5.1, p.57) shows that such help could be obtained on terms that need not distort technology developers' attempts to articulate the terms of their desired intellectual commons. The translation process would also raise a number of issues that would need to be addressed by technology developers themselves because they relate directly to the conditions of access of the common pool resource that would be established by an open source biotechnology licence. This could occur through a combination of "model mongering" and iterative learning, drawing on previous experience in software, biotechnology and any other spheres of production in which commons-based peer production has been seriously attempted.

The outcome of such an evolutionary approach to licence development might not, in fact, resemble open source software licensing very closely, though there would presumably be many shared attributes based both on divergent evolution – similarities due to common ancestry — and convergent evolution – in which similar problems are solved in similar ways. According to the author of the OSD, this is not a matter for concern:

> I do take a purist line about what open source is supposed to be – but only in software. Obviously we are attempting not just to write a licence but to social engineer, and the parameters for successful social

> engineering may be different in different spheres. If we create something that is less than a working community, then this effort has no meaning.[155]

In the next chapter, we step back from the issue of licensing to examine whether and how such a community might coalesce in the biotechnology context.

[155]Bruce Perens, personal communication.

Chapter 6

Open source as a development methodology

6.1 Introduction

We saw in chapter 4 that "open source" may be characterised as a set of principles for technology licensing, as a methodology for technology development, and as a strategy for exploitation of technological innovations.

Chapter 5 addressed the question whether it would be feasible to license biotechnologies in accordance with open source principles that have evolved in a software setting, building on copyright law. We now ask whether an open source approach to technology development could be applied in biotechnology.

To conduct a detailed comparison between open source software development and existing and possible future approaches to biotechnology development, it is necessary to create or adopt an analytical framework in which open source development is characterised in terms of generalised principles, as distinct from principles peculiar to software development. There are many possible ways to map the highly varied landscape of open source, depending on the purpose of the map and the disciplinary background of the cartographer; rather than multiply analyses I have chosen to adopt an analytical framework drawn from the innovation management literature on user innovation.[1]

A user innovation approach has several advantages in constructing a generalised theory of open source development. First, the literature is replete with empirical studies conducted in a range of industrial settings.[2] Second, in part as

[1]The seminal work in the user innovation literature is Eric von Hippel's 1988 book, *Sources of Innovation* (von Hippel (1988)). User innovation theory has its roots in the broader fields of innovation management and industrial organisation.

[2]These include studies of user innovation in relation to printed circuit CAD software (citetUrban1988); pipe hanger hardware (Herstatt & von Hippel (1992)); library information systems (Morrison et al. (2002)); Apache open source server software security features (Franke & von Hippel (2003)); outdoor consumer products (Luthje (2000)); "extreme" sporting equipment (Franke & Shah (2002)); mountain biking equipment (Luthje et al. (2002)); mass production of steel in the nineteenth century United States and the development of personal computers (Meyer (2003)); development of the Cornish pumping engine in the British Industrial Revolution (Nuvolari (2001)); "pultrusion" process machinery and scientific instruments (von Hippel (1988)); wind turbines, agricultural equipment, currency and seeds (Douthwaite (2002)), as well as open source software

a consequence, user innovation theory does not treat the open source phenomenon as sui generis, but places it within a continuum of approaches to promoting and supporting technological innovation. Third, the user innovation literature articulates and challenges assumptions that other branches of literature, including law and economics, tend to leave implicit concerning the way decisions are made about how to exploit innovations and associated intellectual property. Finally, a user innovation approach is compatible with other relevant approaches in that it analyses the motivations of various players in terms of rational self-interest; yet it avoids falling into the trap of equating self-interest with pecuniary interest, to the exclusion of other kinds of benefit. In addition to its inherent advantages, the "user innovation" model of open source software development is highly accessible and already shows signs of winning the competition for "survival of the fittest" within the emerging scholarly niche devoted to studying the open source phenomenon.[3] This means that adopting a user innovation model of open source should help promote inclusive yet nuanced discussion of this phenomenon across disciplinary boundaries.

From a user innovation perspective, open source software development is an example of a horizontal user innovation network supported by a community.[4] A "horizontal user innovation network" is characterised by user innovation, collective invention based on free revealing of innovations, and independence from manufacturers (defined below).[5] This chapter examines each of these elements, together with the element of community support, to determine the extent to which it already exists or could be reproduced in biotechnology. If all the elements of a generalised open source model are actually or potentially present in the biotechnology context, we may conclude that it is possible to implement an open source-style approach to biotechnology development.

6.2 User innovation

6.2.1 What is user innovation?

The user innovation literature draws a distinction between users and manufacturers of an innovation, the categories being defined according to the type of benefit an innovator expects to get from his or her innovation. These categories are termed "functional classes" because they are determined by the innovator's

(see online papers at Free/Open Source Research Community, http://opensource.mit.edu).

[3]The open source literature is fast-growing and multidisciplinary; the phenomenon is of broad interest both because the transparent nature of open source development makes it easy to study empirically and because it challenges conventional assumptions in many disciplines. One of the richest repositories of open source literature is maintained by von Hippel and others at Free/Open Source Research Community, http://opensource.mit.edu/, last accessed 1 November 2004: the collection of online papers available at this site demonstrates the breadth of scholarly interest in this subject.

[4]von Hippel & von Krogh (2001); Lakhani & von Hippel (2002).

[5]von Hippel (2002).

functional relationship to the innovation.[6] A *user* is a person or a firm that benefits primarily from using the innovation in-house. A *manufacturer* is someone who expects to benefit primarily by selling the innovation to users.[7] The conventional assumption is that manufacturers rather than users are likely to be the main innovators in any given field, for the simple reason that "inventing one and selling many" items is assumed to be the most profitable way to exploit an innovation. But according to user innovation theory, all functional classes are potential sources of innovation under appropriate conditions.[8]

To understand why, it is helpful to consider what motivates innovative activity. People and firms sometimes innovate in response to an expectation that they will derive some benefit, either from the innovation itself or from the process of innovating. (Process benefits may or may not be commercial in nature and include fun, learning and a sense of belonging to a community.) Alternatively, if the innovative activity is incidental to the pursuit of some other goal, a person or firm may engage in such activity without expecting any benefit: the innovation is then a side-effect. In other words, not all innovators innovate with the intention of exploiting the innovation itself. Therefore, the functional class whose members have the most to gain by exploiting a putative innovation need not always be the primary innovators in a given field.

Further, even if we limit our focus to innovation that is motivated by an expectation of benefit to be derived from exploitation of the innovation itself, the manufacturer's "invent one, sell many" approach is not always the most profitable means of exploitation. Users are often better placed than manufacturers to capture economic rent from an innovation: for example, users are in a better position than manufacturers to protect trade secrets because selling a technology increases the likelihood that it will be reverse engineered; similarly, manufacturers need to market an innovation in order to extract rent from it, whereas users need only decide whether to adopt a new technology and therefore take less risk.[9] User innovation theory predicts that where users are the best placed to derive benefit from an innovation, they will be the primary innovators, and proposes specific conditions where this is likely to be the case.[10] These conditions are that information is "sticky" and that user need is heterogeneous.

In contexts where the information required to generate new technological developments is "sticky" – that is, costly to transfer in usable form – it makes more sense for a user, who already has most of that information, to engage in innovative activity than it does for a manufacturer, who would have to invest in getting

[6]von Hippel (1988), pp.3-4.

[7]Users and manufacturers are not the only functional classes identified in the literature, though they are the most studied. Like manufacturers, *suppliers* of goods or services needed to produce or use an innovation and wholesale or retail *distributors* of an innovation both benefit indirectly through increased demand resulting from its adoption by users. Other functional classes benefit from increased activity in the sector as a whole, for example insurers and providers of professional services such as lawyers, accountants or fund managers.

[8]Ibid., p.4.

[9]Ibid., pp.46-55.

[10]Ibid., p44.

hold of information about what users need and how a particular innovation functions in a given industrial setting. If user need is also heterogeneous, manufacturers are even less likely to make such an investment, as heterogeneity makes these tasks simultaneously more costly and less rewarding (because the market for any particular product would be correspondingly smaller). In such contexts, the costs of innovating are likely to outweigh the benefits for manufacturers, whereas users will still be able to profit by the internal use of innovations, for example through cost savings or quality improvements.[11] This internal use value (the value of the innovation as an intermediate good, as distinct from its end value or value as a final good) has been shown to suffice as an incentive for innovation in such diverse applications as pultrusion process machinery, semiconductor and printed circuit board assembly, scientific instruments, wind turbines, agricultural equipment, currency and seeds, as well as computer software.[12]

6.2.2 User innovation in biotechnology

Is biotechnology research and development one of those areas where it often makes sense for users to do most of the innovating? If the information surrounding biotechnological innovations is sticky and if the needs of people or firms who will use those innovations are heterogeneous, we may conclude that it is.

The stickiness of information is affected by several factors, including how much information is to be transferred, attributes or choices of information providers or information seekers, and attributes of the information itself.[13] For example, information providers may decide to charge for access to information, while information seekers may lack relevant tools or complementary information or may be less efficient for some other reason at acquiring particular information. (In both cases, the existence of specialised organisational structures such as transfer groups, or specialised personnel such as technological gatekeepers, may affect the ease with which information is transferred.) The qualities of information itself that affect stickiness have been variously described in terms of its degree of "codification", "tacitness", "generalisability", or "embeddedness".[14]

Information surrounding biotechnological innovations is sticky in all of these senses. Recall from chapter 2 Hilgartner's "data stream" theory, grounded in

[11] Franke & von Hippel (2003); Luthje et al. (2002).

[12] Above, note 2. Note that the primacy of user innovation in software development is not confined to open source software, though the fact that the free redistribution clause of open source licences eliminates any direct path for manufacturers to appropriate returns from private investment in open source products means open source is an extreme example. In his essay "The Magic Cauldron", Raymond addresses what he terms "the manufacturing delusion", that is, the assumption that software has the value characteristics (balance of intermediate versus final value) of a typical manufactured good, asserting that approximately 95% of software code is written for internal use. Raymond suggests this assumption persists partly because the small portion of the software industry that manufactures for sale is also the only part that advertises its product: Raymond (2001), chapter 5.

[13] von Hippel (1994).

[14] Polyani (1958); Rosenberg (1982); Nelson (1990); see Mandeville (1996) for a comparison of terminology.

empirical research on access practices in molecular genetics, the foundation science of the biotechnology industry (section 2.4, p.14). According to this model, scientific data are not stable, well-defined entities, but elements of an evolving data stream that are often embedded in tangible objects whose form affects the purposes for which the data can be used: in other words, the information itself has sticky qualities. Further, a variety of attributes and choices of information providers and seekers have the capacity to hinder the flow of scientific data, including the diversity of actors within research networks and the wide range of mechanisms available for granting, limiting or denying access to data. In particular, strategies for commercialisation, including intellectual property licensing practices, often increase the "stickiness" of biological data: as described in introductory chapters, this aspect of information stickiness is the motivation for the present investigation. As for stickiness arising from uncertainty as to the amount of data to be transferred or the need to transfer large amounts of data, this is implicit in the conceptualisation of data as a continuously flowing stream that cannot readily be partitioned into separate "bites".

The following comment by a senior scientist involved in efforts to model a biological system of importance to the pharmaceutical industry illustrates how the complexity of biological systems themselves and the early stage of development of many biotechnologies contributes to the phenomenon of information stickiness in biotechnology:

> The systems we're trying to decipher are incredibly complicated. Someone told me a joke: "How does a biologist try to figure out how an automobile works?" Answer: "He buys a thousand cars, shoots a piece off each one and tries to figure out what happened." So we have a lot of new technologies for trying to understand how biological systems work, but [although] it is very sophisticated in one sense, in another it's really not. And we're not just dealing with a two or even a three dimensional problem; it's four or five dimensional, things are happening over time, it's a moving target. ... There is data we still have not shared yet because the rate limiting step has been developing the tools to import, store, analyse and display the data.[15]

Another comment by a biological engineer illustrates the stickiness of biotechnology-related information with respect to both attributes or choices of information providers or information seekers, and attributes of the information itself – at the same time recalling its stickiness in a literal sense:

> People talk as though DNA is pure information, but there is more information contained in the molecules [than just] the sequence information... because... it is not easy to obtain DNA simply by synthesis from a published sequence....
> There are three ways you would normally go about [obtaining molecular DNA]. The first is to "clone by phone". Journals require that

[15] Alfred Gilman, personal communication.

> you share with anyone who phones you up and asks, but there is no enforcement....Your next option, if they refuse, is to somehow obtain a sample [of the organism from which the sequenced clone was initially derived] and clone it yourself. That is difficult; it takes some work and also some time waiting for the sample to arrive, and there is a problem if the sample itself is dangerous – if you want to work on smallpox DNA you don't really want to be culturing smallpox in your own lab. Your third [option] is to order synthetic DNA based on the sequence. Right now that is a crazy, desperate last resort; it's costly and you have to have it done in short sequences because you cannot make a long piece of DNA easily: it's fragile, and as you're working on one end, the end you have already made starts sticking to itself, goes bioactive and starts doing things you don't want it to do.
> Over the next five or ten years, it will become much more realistic to genuinely build DNA from a sequence, and [then] I predict people will...find new ways to slow things down. People get sneaky: there was this guy who got published in one of the big journals and somebody wrote to ask for a sample of DNA and he said no. They were so angry they shredded up the refusal letter and did PCR on it and managed to clone the sequences off it – it had been lying around the other guy's laboratory and there was a whole lot of DNA stuck to the paper![16]

Not only is biotechnology information sticky, but user need is often heterogeneous. One type of heterogeneity relates to the scale of research projects: in biotechnology, "big" science coexists with traditional biology research led by individual investigators in single laboratories with a handful of staff. The scale of a project has a direct impact on users' ability and willingness to pay for innovations developed by manufacturers for a broad market, and can therefore tip the balance from manufacturer innovation towards user innovation:

> Whether you can afford off-the-shelf technology depends on what you are trying to do. [Ready-made cDNA arrays] might be quite reasonably priced for some purposes, but one of the first experiments we did required several hundred arrays, and Affymetrix was pricing their arrays at thousands of dollars apiece, so it would have cost us several hundred thousand dollars to do the experiment. The sheer scale of what we're doing here means things aren't always affordable.[17]

At the other extreme, in-house adaptation of an existing tool – a process sometimes known affectionately as "bodging", familiar to every home handyperson and also every lab technician – will often be more cost-effective for a small or short-term project than the purchase of manufactured tools specific to the task.

[16]Tom Knight, personal communication.
[17]Alfred Gilman, personal communication.

innovation – analogous, perhaps, to farmer experimentation with the application of fertilisers to Green Revolution crops[27] – may be considered peripheral. But though it is true they do not relate directly to the use of biotechnologies to develop the composition of a drug, many of these developments do involve the application of biotechnology-related knowledge, are patentable and are regarded by pharmaceutical companies as valuable enough to be included in "total product" or "lifecycle maximisation" patenting strategies, in which intellectual property owners erect "picket fences" or families of dozens of patents around a single product covering numerous aspects of the product.[28]

6.3 Free revealing

6.3.1 Proprietary and non-proprietary exploitation strategies

In the previous section we saw that user innovation theory challenges the assumption that manufacturers dominate innovation. A second assumption underpinning conventional theory is that any uncompensated spillover of proprietary knowledge developed through private investment will reduce the innovator's profit from that investment. The user innovation literature challenges this assumption also, returning to first principles to compare the likely costs and benefits of proprietary and non-proprietary strategies for exploiting an innovation.[29] Proprietary strategies include both in-house use and licensing of innovations protected by IP laws (such as copyright or patents) and trade secrecy. The essence of any proprietary strategy is exclusion – to preserve a competitive advantage conferred by the innovation, and in the case of licensing out, to prevent non-licensees from reaping the benefits of the innovation without paying, which would erode potential licensees' incentive to enter a licence agreement in the first place and thereby prevent the owner from recovering any revenue. By contrast, non-proprietary strategies – termed "free revealing" in the user innovation literature – entail granting access to an innovation to all interested agents without imposition of any direct payment. According to the literature definition, free revealing does not mean that recipients necessarily acquire and utilise the revealed information at no cost to themselves (for example, they may have to pay for an Internet connection or a field trip to acquire the information being freely revealed or may need to obtain complementary information or other assets in order to fully understand that information or put it to use); however, if the information possessor does not profit from any such expenditures made by information recipients, the information itself is still freely revealed.[30] Technology licensed according to

(1997), referring to the influence of HIV/AIDS patients on clinical trial techniques in the development by Merck of protease inhibitor drugs.

[27]Douthwaite, op.cit. note 24.

[28]European Generic Medicines Association, "Patents and Lifecycle maximisation", http://www.egagenerics.com/gen-phrmapatents.htm, last accessed 3 November 2004.

[29]Harhoff et al. (2002).

[30]von Hippel (2002).

open source principles is, of course, privately owned, but because open source licences allow use, redistribution and modification of subject matter without imposing any fee, open source licensing has been characterised in efforts to map the public domain as "contiguous territory"[31] and falls within the user innovation literature definition of "free revealing". Free revealing may be adopted as a deliberate strategy, but it may also be the default if the necessary steps are not taken to either keep an innovation secret or obtain intellectual property protection for it.

A comparison of these strategies indicates that although a proprietary approach is often the most profitable way to exploit an innovation, this is not always the case. On the one hand, there are important limitations inherent in any proprietary strategy. For example, consider a strategy based on secrecy. Trade secrecy only makes sense for inventions that either can be commercially exploited in secret or cannot be easily reverse-engineered; further, even though there is no limit to the term of protection in principle, in practice it has been shown that most secrets cannot be kept longer than 12 to 18 months.[32] The costs of preserving secrecy can be significant and must be set off against the benefits of exclusive access. Further, when it comes to licensing an innovation outside the innovation organisation, a dilemma arises: disclosing the information to too many people can result in the loss of legal protection, but disclosing to only a small number places a cap on the amount of licensing revenue that can be derived from the innovation.[33] Similarly, there are disadvantages to a proprietary approach based on intellectual property protection; we return to this point below.

On the other hand, the user innovation literature documents a number of ways in which a self-interested innovator can benefit from a non-proprietary (free revealing) exploitation strategy. In the discussion that follows, we consider three examples relevant to a commercial setting.[34] First, free revealing may grow the user base for a technology, thereby growing the market for complementary goods and services and perhaps even establishing a de facto industry standard. Second, free revealing may increase the value of an innovation to the innovating user. If this increase in value is due to network effects, it will be a direct result of growing the user base of the technology (in other words, these first two types of benefit overlap). Such an increase in value could also be due to a "certification signal" or "peer review" effect that enables the innovating user to treat the technology as reliable on the basis that it has been tested or checked by other users.[35] Neither of these enhancements in use value depends on allowing others to modify the innovation; if the mechanism by which the innovation is freely revealed does facilitate improvements to the core technology by other users, there may be further benefits for the innovating user. For example, a manufacturer may develop a new version of the innovation that leads to reduced production costs or in-

[31]Samuelson (2001)
[32]Mansfield (1985), cited by Von Hippel in *Sources of Innovation*.
[33]Harhoff et al. (2002).
[34]Ibid.
[35]Meyer (2003).

> In high tech, one of the keys to the development of markets is the establishment of standards. Secretly everyone wants to be Microsoft and establish a de facto proprietary standard; but most people recognise that the Microsofts and the Intels are going to be few and far between.... .So given a choice between a proprietary approach which is going to be stuck in a niche because it is proprietary, and a potentially very big business opportunity that's large because it's based on a standard, the standard-based approach may be rational. In this thinking, you could justify a non-proprietary approach where you make money off of supporting it, off other complementary things, off integrating it into other things. These opportunities might be harder to find in biotechnology than in software, but they probably do exist.[42]

For example, there could be an opportunity for an "open source" biotechnology firm in selling instrumentation that would conform to an open standard for making microarrays. As we saw earlier, at present proprietary chips are too expensive for some users and some applications; as a result there is a ready-made customer base for tools that would enable users to "roll their own" microarrays in accordance with a format that would ensure compatibility with other users' data:

> Affymetrix [a proprietary microarray manufacturer] is probably the closest thing we have to an Intel in the life sciences tool business, and one of the reasons... is that microarray expression data is not comparable across different microarray technologies. So once you have some Affy data, if you want to use it in the context of any other microarray data, you've kind of got to have that other data in Affymetrix format – in other words, use more Affy chips. The same is true for people who "roll their own" arrays – the data they generate can't be compared to anyone else's data. If someone could develop a way of normalising data from different microarray formats, that would be a huge opportunity for a whole bunch of people, not only on the [informatics] side, but also for microarray manufacturers and users. So that would be another area where you have a de facto [proprietary] standard but you could create an official, open standard. The only people for whom that would be bad news would be the owners of the proprietary standard.[43]

Another example might be in the area of assessing the safety of new drugs:

> [Toxicology] is an area where there's a big need for tools – and wherever there's a need that big for tools there's the possibility of coming up with a standardised approach that would grow the overall size of the opportunity and benefit a lot of people.[44]

[42] Lee Bendeckgey, personal communication.
[43] Lee Bendeckgey, personal communication.
[44] Lee Bendeckgey, personal communication.

A second potential commercial application of a free revealing strategy aimed at growing the user base for a technology would be to pre-empt the establishment of a proprietary standard (in this context, free revealing is often referred to as "defensive publishing"). In biology, the ultimate technical standard is the human genome: it is the platform on which every human genetic technology rests, and it is entirely and forever non-substitutable. Private ownership of the genome would be a disaster for everyone but the owner, and it is therefore not surprising that this is one area where free revealing has taken root in an otherwise highly competitive industry. The most obvious example of this strategy is the participation of large pharmaceutical companies in the SNP consortium (TSC),[45] which funds academic scientists to collaborate in the creation of a public database of human genetic markers.[46] Funding the creation of a public SNP map of the human genome is a way of sidestepping a potential "tragedy of the anticommons" in relation to SNP data:

> [With SNPs,] as with ESTs and then with the complete human sequence, there was a fear that the gold rush mentality would lead to large numbers of SNPs being tied up in patents and pooled beyond the reach of further research.[47]

For the various commercial members of the consortium, opting out of intellectual property ownership meant not having to negotiate subsequently for access to intellectual property either among themselves or with smaller biotechnology firms – a move that has been described as "placing a blocking stone on the go board".[48]

In the case of ESTs (Expressed Sequence Tags), the free revealing strategy was employed by a single firm funding academic research, rather than a consortium:

> The big companies weren't any happier than the academics that upstart genomics companies looked like cornering all the rights to valuable genome information. Merck funded a massive drive to generate ESTs and place them in the public databases, where they would be freely available to all. ... By doing this, Merck not only gave the entire research community, public and private, free access to valuable genomic data; it also made those sequences (and possibly the whole genes from which they came) much more difficult to patent.[49]

[45]The TSC is a public-private collaboration jointly funded by the UK's Wellcome Trust and ten major pharmaceutical companies: AstraZeneca, Bayer, Bristol-Myers Squibb, Glaxo Wellcome, Hoechst Marion Roussel, Hoffman-La Roche, Novartis, Pfizer, Searle and SmithKline Beecham: http://www.ims-global.com/insight/news_story/news_story_990925a.htm, last accessed 20 November 2004.

[46]The leading research institutions participating in this effort are the Whitehead Institute/MIT Center for Genome Research, Washington University, the Wellcome Trust's Sanger Centre near Cambridge (UK), Stanford University, and the Cold Spring Harbor Laboratory: The SNP Consortium "Frequently Asked Questions", http://snp.cshl.org/about/faq.shtml, last accessed 3 November 2004.

[47]Sulston & Ferry (2002), p.199.

[48]Roger Brent, Open Source Biology workshop.

[49]Ibid., p.119.

While it is easiest to find examples of pre-emptive free revealing in relation to human genome data, there are other contexts in which this type of strategy could make sense. The context of the following exchange was that pharmaceutical companies could be expected to be keen to forestall the establishment of a proprietary standard in predictive toxicology (see further discussion below):

> Bendeckgey: There are almost inevitably going to be technologies developed that have great value to [pharmaceutical companies]..., and [so] they will definitely want choice of suppliers. Having a supplier of a critical value driver be the sole source for that thing is really your worst nightmare.
> Hope: So does that mean these larger companies might be prepared to support a new enterprise that was based on trying to come up with an open source tool?
> Bendeckgey: I think if you had a credible story, they might, yes. ... Even though pharmaceutical companies have a history of not liking sharing, one thing they like even less is being beholden to an Intel or a Microsoft – or an Affymetrix.[50]

This point is worth emphasising: large downstream players in the life sciences, as in other technology fields, will always want competition among their suppliers, and could be expected to support open source to the extent that it helps achieve this goal.

Induced improvements The second type of free revealing benefit listed above is that an innovator who intends to use the technology may gain access to valuable improvements made by other users for their own purposes:

> [W]hen as a company you spend that money it's like putting bread on the waters, because what happens is you stimulate all these research areas, you already have a lot of interests in there and you may then pick up a lot of things from that research that may be advantageous to your business. So...these things can very well pay off. Sometimes you are just as well off, or better off making the thing public because... you'll reel in bigger fish yourself by putting it out there. ... If people take the longer vision then they must benefit from this, because their particular product will become more widely used and therefore richer. [51]

For obvious reasons, this motivation often sits alongside pre-emptive publishing as a reason for adopting a free revealing strategy, as in the case of the TSC:

> A high-quality, high-density SNP map is a research tool that will benefit everyone involved in genomic research. By collaborating, the

[50] Lee Bendeckgey, personal communication.
[51] John Sulston, personal communication.

> members of The SNP Consortium will be able to create a commonly-accepted SNP map more quickly, and with shared financial risk and less duplication of effort than if each company proceeded on its own. Additionally, The Consortium anticipates that the map that will be constructed will be of greater density and therefore potentially greater utility to the pharmaceutical industry than SNP maps currently available.[52]

This type of collaboration is best suited to fundamental enabling technologies that are not a source of competitive advantage for the companies involved:[53]:

> [F]ive years ago, bioinformatics companies were coming into existence at a rate of several new companies a day, offering to solve the problem of a huge amount of data – managing, correlating, mining data – but none of them ever really made a business of it. ...[S]omewhere along the line the pharma companies decided to...build their own bioinformatics organisations, and they were all convinced their way was the best. ... There's got to be a lot of private grumbling going on in pharmaceutical companies about that, because now they're stuck with all this overhead... . One can imagine that if someone could [develop an open standard for bioinformatics], that would ultimately be a huge win for them. Their R&D budgets are under enormous pressure – especially for anything that doesn't involve getting a drug through the clinic and onto the market.[54]

Thus, large companies may be expected to support an open source approach where it complements their proprietary business models by reducing costs, risks and product development time.

Other examples of important technologies that would benefit from constant evolution and improvement where this kind of approach might be useful include toxicology and management of clinical trial data. In relation to toxicology, the difficulty for pharmaceutical firms was once a scarcity of promising drug targets; with the advent of genomics this is less of a problem, and the major bottleneck is now that many drug candidates fail too late, after enormous investments have been made. Some efforts are being made within the industry to develop predictive toxicology tools, but fundamentally the process still consists, as one interviewee put it, of "lining up rats, dosing them and seeing which of the little buggers die". A tool that could identify unpromising drug candidates either predictively or by early analysis of the toxicology profile before they reach the second or third phase of clinical trials would save pharmaceutical companies a huge amount of money and cut a lot of time off the drug development process.[55]

[52]The SNP Consortium, "Frequently Asked Questions", http://snp.cshl.org/about/faq.shtml, last accessed 3 November 2004.

[53]Sulston & Ferry (2002), pp.199-200.

[54]Lee Bendeckgey, personal communication.

[55]Ibid.

In relation to the management of clinical trial data, this is still a surprisingly manual process; nurses and doctors at university hospitals "write things down in pen and ink and make stacks of little pieces of paper and send them back to the company".[56] According to interviewees, the process is inefficient and error-prone in circumstances where errors have important regulatory and product consequences, and is another area where pharmaceutical companies are spending large amounts of money on a process which is not a major source of competitive advantage:

> I can't see that in this area they would think it was so important to have a proprietary version [of a management tool] that was better than anyone else's, so again this is a big need where they probably wouldn't be averse to sharing.[57]

As we saw in chapter 3, such shared or collaborative technology development is often plagued by problems of trust; in the absence of an effective mechanism to enforce sharing, free revealing with the aim of obtaining this type of benefit therefore carries some risk. Pharmaceutical companies have even been wary of licensing in data under a non-exclusive licence:

> Pharma would be... suspicious. ... [T]hey like to keep things close to their vests. For example, the economics of selling databases of proteins, genes and so on are only really attractive if you can resell the same data to many customers. It took a while to convince... the first [customers for these products] that it really didn't put them at a disadvantage to share the information with other pharmaceutical companies – that is, with other customers; that ultimately... they could get more information and a higher quality of information through sharing the expense of generating it with multiple companies buying the same information than either doing it themselves in-house or paying someone exclusively to do it for them.[58]

However, as we saw in chapter 5, non-exclusive licensing arrangements with grant-backs of rights in improvements (somewhat analogous to a copyleft approach) sometimes bring sufficient benefits to participants for them to overcome their mutual suspicion, as demonstrated by the following example concerning Incyte Genomics' database licensing arrangements in the early 1990s:

> Besides providing access to information about genes and proteins, Incyte gives its customers the right to use any patents that it has on the genes and proteins described in its database; so to the extent we have intellectual property, you get freedom to operate, you're not just looking at it on the computer. In those days it was mostly ESTs. ... [I]t occured to the folks at Incyte and Pfizer late in negotiatons [for Incyte's

[56]Ibid.
[57]Ibid.
[58]Ibid.

> first database product] that Incyte could be inadvertently starting an arms race among the pharmaceutical companies in the following way. Like any good pharma company that lives and dies by its IP portfolio, one thing Pfizer insisted on – like basically all others, in negotiations – was that if they discovered the full-length gene based on a partial gene in our database, and figured out its function, they could patent that: it would be theirs, not ours. That seems fair, but then it started to occur to everyone that it was quite likely, given everyone was starting with the same data, that people would identify a lot of the same partial genes as being of interest, and then you would get this kind of race in which everyone was racing to complete the gene and figure out its function and get the IP on it and then start lobbing legal missiles at all the others. [T]here started to be concern [that] people would be contaminated and face the risk of IP infringement actions from other people who were using the same data. So what was proposed, and what Pfizer agreed to in the first agreement, and every big pharmaceutical company has agreed to since then, is in effect an open source-like grant-back. What those agreements say is that if any of our database users discovers and characterises a full-length gene using the information in our database, they grant back to Incyte and to all other users of our database non-exclusive freedom to operate... to use it as a target for your own drug discovery. This was actually before open source, but... it's actually the same concept: you have all these people working with the same starting point, and if they generate what can be thought of as an improvement – you know, added value – it gets granted back to everybody else. For Incyte itself, ... it removes the impediment [to selling the database], which was the original benefit, and now there is the additional benefit that it is perceived as an additional source of value: they're not just getting access to our IP, they are also getting access to the IP of all of these other pharmaceutical companies who have been working with this data for some significant period of time. So that is really the benefit to us, it increases the value of the product we are offering. So that story illustrates that they can be persuaded to share, but it's not easy – and the closer you get to the end product the harder the task of persuading them will be.[59]

The reason for emphasising free revealing involving pharmaceutical companies is not that these are the only examples within the biotechnology industry, or even the most closely analogous to the open source approach. It is that these examples are robust: pharmaceutical companies are notoriously reluctant to co-operate with one another, so if it is possible to cite instances where these companies were prepared to adopt a free revealing strategy, it is reasonable to assume that there will be other examples in sectors of the industry that lack such a history of fierce competition.

[59]Ibid.

in favour of a free revealing approach, though as we saw in the previous section, such an approach might be appealing in relation to research tools.[69]

The upper limit on potential licensing revenue represents the size of the opportunity cost of free revealing in relation to a proprietary strategy based on licensing the innovation out for others to exploit in exchange for licence fees or other valuable considerations (for example, concessions in a joint venture agreement or access to other technology through cross-licensing).[70] If an innovator would instead have chosen to exploit the relevant technology in-house, the opportunity cost associated with free revealing would be the erosion of the competitive edge achieved through the use of the technology due to "free riding". The size of this opportunity cost depends on the circumstances. Free riding is not a cost if the innovator would not have been able to commercialise the innovation anyway, for example because the innovator is either not in business at all or is in a different business and the costs of changing the business model in order to exploit the innovation would be too high. In fact, free riders may be assets in that they may increase the impact of or exposure to an innovation, or if they are free riders in one respect but contribute in other respects, for example through beta testing or word of mouth marketing. The size of any loss from free riding will be greater the more intense the competition in the relevant field; in considering the intensity of competition, the existing pattern of competition across the whole industry should be taken into account as well as possible changes to the nature of that competition that may be effected by the innovation itself.[71] For example, although each firm in a given geographical area may be engaged in fierce competition with other local firms, collectively they may compete against other regions or sectors of the industry and therefore may have an incentive to work together as a competitive unit; information stickiness may mean that even though an innovation is freely revealed, diffusion may be more effective within a tighter-knit or geographically localised group of firms.[72] One reason competition may be weak is due to the existence of distinct groups of consumers or geographical segregation within a market:

> Informant: At a certain point during expansion, there will be... enough service providers in the area in this particular niche to saturate the market, and then if there are some more they will start competing, as in... any biological system – ...there has to be a combination of competition and cooperation. ... I think there is no doubt that we could accommodate 20, maybe 100 technology providers in all the geographic and other market niches that can be identified. So that is why identifying people from many different backgrounds, different kinds of organisations, allows us to have a better penetration; if we [deter-

[69] Even with respect to drugs, this is not always a foregone conclusion: see below, p.173.

[70] von Hippel (1988), pp.46-55.

[71] Harhoff et al. (2002).

[72] Peter Drahos (personal communication) suggests that geographical indications might be seen as "fossil evidence" of such localised systems.

> mine in advance who can] join the network, then we are losing that whole... opportunity that we could have by generating a diversity of players in the network. So it has to be open to everybody.
> Hope: So, is the geographical distribution of the market – that is of potential customers for these technologies – the biggest problem that you are dealing with...?
> Informant: It's not a problem. It is an opportunity.[73]

Further, free riding represents only a small loss if the innovation is highly specific to the user-innovator and there are no complementary profits available to other users or there is a long response time for imitators.[74] With respect to this last point, one difference between the software and biotechnology contexts is that product cycles are longer in biotechnology. As product cycle times drop, free riding becomes less of a threat because the pay-off period shrinks relative to the time imitators have to spend copying the technology, and it has been suggested that free revealing is therefore more likely to be attractive in software than in biotechnology.[75] The answer to this is that while product cycles for drugs are much longer than for software programs, other biotechnology-related innovations have product cycle times that are comparable to software:

> Technologies develop in a similar way to empires: they are born, they develop, they plateau, they die. ... In genotyping, every technology [has] about three or four years from the concept to uptake and then five years of very smooth operation and taking a lot of the market, and then they slowly start to die out because there is another new thing coming. ... Plant breeding is something like that too – the turnover of cultivars is only a few years. And so everything has turnover and it can be quite rapid.[76]

In relation to some biotechnology-related products, product cycle times may be far shorter:

> In the case of biological databases, tiny updates are all that are being sold, and they come out very frequently. Companies would pay a big premium in order to get Genbank every twenty-four hours... .[77]

Related to the issue of opportunity costs of free revealing is the issue of the cost of innovating. It is sometimes argued that the cost of innovating in biotechnology is too high for innovators to be satisfied with what are assumed to be lower returns associated with a free revealing strategy compared with an exclusive proprietary approach.[78] The cost of innovating in biotechnology is discussed

[73] Anonymous informants: senior executives, small plant biotechnology firm.
[74] von Hippel (1988), p.84.
[75] John Barton, personal communication.
[76] Andrzej Kilian, personal communication.
[77] Stephen Maurer, personal communication.
[78] Open Source Biology workshop.

in detail in a later section (6.5, p.180ff); but note that different motivations for innovating have different implications regarding the importance of cost. If the innovative activity is undertaken in the expectation of benefiting from the innovation itself, then cost matters, and a successful innovator will very likely pursue an exploitation strategy calculated to bring the greatest return on investment. If the innovative activity is incidental to another activity, the incremental cost of innovating is (by definition) zero or close to zero, while if the innovative activity itself generates the expected benefit (for example, fun or learning), the incremental cost of innovating will be negative.[79] In these cases the absolute cost of engaging in innovative activity may constitute a barrier to innovation, but if innovation does occur, the innovator will not necessarily seek to exploit the resulting technology for profit.

Actual costs So far we have looked at the opportunity costs associated with free revealing. We now turn to actual costs. Unlike obtaining patent protection, free revealing involves no registration or maintenance fees, but at least to the extent that it is adopted as a deliberate exploitation strategy and not merely a default, free revealing generally requires considerable input from the innovator in order to ensure uptake of the technology.[80] For example, von Hippel observes that innovators may sometimes choose to subsidise the acquisition and evaluation and use of their freely revealed information by investing in extensive and expensive lobbying to get others to adopt a technical standard.[81]

Often there is considerable preparation involved even in getting an innovation ready to be released:

> The people that worked on [a project that didn't generate a new product] are thinking, "I put a few years into this thing and look what's happened. Maybe we should give it to the world." That might be the right thing to do in some circumstances, but there are ... a lot of hidden costs associated with properly handing off code publicly, so you really have to weigh the benefit of making it available for free, versus the costs.... There is a lot of code scrubbing that has to be done to be sure that it is suitable for public consumption.[82]

As Hilgartner points out (see section 2.4, p.13), this state of "readiness" is not an objective property of the technology but a matter of judgement as to whether the innovation is sufficiently useful in its current form, in terms of reliability, reproducibility and other aspects related to the degree of codification of the relevant information, to interest the target audience: as has been remarked in the software

[79] Franke & Shah (2002).

[80] Of course, this is also true for any proprietary strategy based on licensing the technology to others.

[81] von Hippel (2002).

[82] Bill Lard, in Rosen et al. (2003), p.59.

context, "you don't just throw your garbage into the street".[83] In the case of software source code, typical tasks carried out in preparation for release (in addition to quality and legal checks) include making sure there are no inappropriate comments mixed in with the code such as people's names, foul language and so on.[84] In the case of biological materials, we have seen that in order to be useful the material must be transferred together with certain technical descriptions and instructions; some experimentation may be required to find the best way to transfer living materials.

As to actually making the innovation available to others, in the software case, working examples of an innovation – the running code – can be cheaply and instantaneously distributed to a large number of recipients. In the biotechnology case, although it is possible to reveal just the information component of goods that also have non-information content, this will still be expensive if the information is highly uncodified, and as we have seen, effective diffusion of biotechology-related innovations generally requires the transfer of embodied or physical products such as biological materials. Thus, the diffusion costs associated with freely revealing a biotechnology-related innovation are likely to be higher (for both donor and recipient) than they are in software:[85]

> [If] we have to exchange... tangible materials,... it takes time, money, to ship, to pull out from the freezer and stuff like that. ... Even just to do it physically, it's not like pressing a button and sending an attachment by email. [It's a waste if] someone asks for 100 plates and then throws them into the bin... .[86]

The question arises whether sufficiently low-cost diffusion can be achieved in a biotechnology context for a free revealing strategy to be cost-effective.[87] This means that many, probably most, innovations will likely be of relatively low benefit to both diffusers and adopters and so must be diffused at a low cost if they are to be diffused at all: recall from chapter 3 Eisenberg's finding that low value exchanges were more likely than high value exchanges to be disrupted due to high transaction costs.[88] We touch on this issue again later in this chapter (section 6.6.2, p.197), but the following points are worth noting. First, although some methods of transferring information are always relatively low cost – the Internet is an example that is very important to free revealing of software, and some

[83]Ibid.

[84]Ibid., p.60.

[85]Recall from chapter 2 Mandeville's point that the costs of diffusing innovation-related information (including working copies of an innovation) are incurred by both the donor and the recipient of the information. In both cases the incentive to incur the costs depends on the expected benefits; that is, both parties to the transaction will only incur diffusion costs that can be justified against the benefits they expect to receive from innovation diffusion: Mandeville (1996), pp.65-66.

[86]Andrzej Kilian, personal communication.

[87]It has been shown that innovation streams having a large cumulative impact are likely to be made up of relatively small individual innovations. Nuvolari (2001).

[88]Eisenberg (2001), p.234.

types of biotechnology-related information can be transferred in this way – others are episodically low cost: information may be stored in batches to be transferred when costs are low from time to time.[89] For example, scientific meetings or laboratory staff exchanges provide opportunities for the transfer of many pieces of information at low incremental cost for each piece. Episodically low-cost methods of transferring information may in fact have advantages over consistently low cost methods such as Internet and e-mail for the transfer of certain types of information (especially uncodified information); further, different methods are not mutually exclusive but can be used in combination – for example, open source software developers use a combination of electronic communication and rare but highly effective face-to-face meetings (such as "hackathons").[90] Second, as noted in the previous section, free revealing is not unique to software or other information goods, so the mere fact that free revealing of biotechnology-related innovations will usually involve the transfer of tangible materials and uncodified information does not mean it can never be a cost-effective strategy. Such innovations have traditionally been freely revealed in the academic context without creating an overwhelming cost burden for researchers; while this says nothing about cost-effectiveness (as academic researchers are not generally required to be economically self-sufficient), it does suggest that the absolute costs of free revealing in this field are within reasonable limits.

A strategic calculation

Clearly, choosing the best strategy for exploiting any particular innovation is a trade-off: a non-proprietary strategy is not universally applicable, in software development, in biotechnology or anywhere else. The outcome of this trade-off will be contingent on the circumstances of each case. However, it is possible to identify some of the factors an innovator will wish to take into account.

Factors influencing choice of exploitation strategy These include the intensity of competition in the particular field, whether the innovation itself has any inherent bias that favours the innovator over competitors, the likely value to an innovating user of any improvements that free revealing may induce others to make and reveal, the likely increase in value of complementary assets (including intangibles like goodwill and reputation) if a free revealing strategy is adopted, the size of the opportunity cost and the actual costs of free revealing. The impact of community expectations or industry norms may also be a factor. For example, pressure from other companies may be applied to restrain "rogue" firms that take the proprietary approach too far:

> Myriad... are very much in the position that Roche were in over the thermostable polymerases, and more and more what I'm hearing from [other people in the] industry is not anymore "Oh, you know it

[89] von Hippel (2002).

[90] Brian Behlendorf, personal communication.

> is perfectly reasonable to patent genes as long as they are out of the body", but "Oh yes, but you're exaggerating because Myriad is an extreme case – we know *they* are bad". ...[W]hat I'm hearing in the business is that Myriad is becoming something of an embarrassment [for those who support a proprietary model], just as Roche became an embarrassment.[91]

(Of course, such restraints are not applied on the basis of any objective standard, but are a response to deviations from the industry norm, which interviewees generally reported as increasingly proprietary – a trend that may be accompanied by a decline in corporate social conscience across the board.)

In the software context, Eric S. Raymond has identified a number of conditions that may weight the outcome of the proprietary versus non-proprietary trade-off in favour of a free revealing approach.[92] These are, first, that the innovative technology establishes a common infrastructure, or in other words, that network effects in relation to the technology are particularly strong. Second, the technology is business-critical to its users, which means they will place a high value on not being beholden to a single supplier. Third, the reliability, stability or scalability of the technology is very important (the assumption being that ongoing development of the technology by way of mechanisms based on free revealing, such as open source, produce better tools than do proprietary mechanisms). Fourth, peer review is needed to verify the correctness of design or implementation. Fifth, key methods or functional equivalents of key methods implemented by the technology are common technical knowledge in the field, implying that a proprietary approach would not necessarily be very profitable and thus the opportunity cost of adopting a free revealing approach would be low.[93]

Raymond's final condition favouring a free revealing strategy is that the innovation is an enabling technology or a scientific resource that represents a non-substitutable standard. An example in medical biotechnology would be the human genome; in agricultural biotechnology it might be selectable markers and transformation tools:

> To put a gene inside a plant cell and then to be able to know it is

[91] John Sulston, personal communication. Douthwaite documents the influence of other agricultural biotechnology firms, concerned about public relations effects across the board, in restraining Monsanto's aggressively proprietary behaviour in relation to genetically modified crops (Douthwaite (2002), p.257); the recent controversy over "junk DNA" patents held by Melbourne firm Genetic Technologies Ltd is another example of this phenomenon. Noble (2003).

[92] Raymond (2001), chapter 5: "The Magic Cauldron". See also Behlendorf (1999).

[93] This condition suggests that the outcome of the trade-off may well change over the lifetime of the tool: early on, it may be better from an economic perspective to keep it proprietary; later it may be better to let it go open source, and the question will often be, as Raymond puts it, "when to let go". In this regard it is worth noting that many owners of patented research tools allow patent protection to lapse over the economic life of the tool; open source licensing could be seen as an alternative to allowing the tool to return straight into the public domain, and the question for the owner would then be whether the advantages expected from an open source approach would make up for the cost of maintaining protection.

there – there are only so many ways to skin this cat.[94]

Bruce Perens, author of the Open Source Definition, explains the distinction between "enabling" software and "differentiating" software:

> Differentiating software gives someone a reason to buy you rather than your competitor; but no-one really cares about your command line, for example. ... I define it as a tree structure. Linux kernel [might be] the roots and trunk of the tree; your software libraries and perhaps the Apache server are the branches, and applications are the leaf nodes, applications that do not block anything else, that is not depended on by other software and not essential... . So on the tree, it is perfectly fine if the leaves are proprietary. But I would never want an essential facility in Linux to be proprietary; it would defeat our purpose.[95]

Greg Graff, one of the initiators of the Public Intellectual Property Resource for Agriculture, comments:

> The tree is a pretty good analogy. The... difficulty is... it's asking a lot to expect people to make that differentiation. ...[P]eople bandy around terms like "enabling technology" and "research tools" versus "trait technology" or "implementation". ... [T]here *are* some rules of thumb, but when you get down to the nitty-gritty for an individual technology it's going to be pretty tough [because] biological technology does not lend itself very well to this basic-versus-applied, trunk-versus-leaf structure.[96] ... [Because] DNA exists in all living things, even the final product for sale, especially in agriculture, still contains all the coding, all the source code, everything. So it is simultaneously reverse engineerable, a very basic technology, and a very applied technology. In other words, you don't have a tree: you have a shrub.[97]

This kind of uncertainty, as we saw in chapter 3, opens the gate to cognitive bias and other non-rational influences on decision-making. As a result, the proprietary versus non-proprietary trade-off may be weighted towards the more conservative approach:

> From the outside it all looks really great – but from the inside there is fear, you're dealing with uncertainty, trust, you're dealing with issues that are hard to overcome. [The open source approach resembles] a model that a lot of people have proposed for the music industry. Well, music is infinitely perfectly replicable: forget about making money from that, make money from live performances, ancillary

[94]Greg Graff, personal communication.

[95]Bruce Perens, personal communication.

[96]Neither necessarily does software; vendors often have trouble deciding whether they have a "niche" or a "platform" product: Spolsky (2004).

[97]Greg Graff, personal communication.

> products... . But... the hook has not been set..., because everybody is terrified to let go of even the shrinking revenue stream that they have now in order to try something new.[98]

Uncertainty breeds conservatism One manifestation of this uncertainty-induced conservatism is an unwillingness to consider the peculiar role of each technology in creating a competitive advantage for the firm:

> Tiemann: [T]here is this bipolar disorder that occurs in the technology industry. You either think a technology is so completely commodity and boring... that you are just going to go and buy it and never even think about looking at it; it is just some cheap thing and you don't give a damn. At the other end of the polarity you say, "This [technology] is totally strategic to our business, and it is so strategic that we have to develop it ourselves, because – heaven forbid – if we develop a dependency on a third party supplier, we will be making them rich instead of us." And there is no middle ground between those two. I think that the open source model says there can actually be a pretty broad continuum there: you can take something that is today's commodity and actually build value into it, make it even more appropriate to your mission...; but right now I think biotechnology is stuck in the bipolar disorder.
> Hope: Is it that people are confused about what it is that they are really trying to sell?
> Tiemann: That could be it. It may just be that human beings... can only see things in black and white sometimes.[99]

In this regard, one major influence on the type of strategy adopted by biotechnology industry participants is the traditional emphasis on a strongly proprietary approach to intellectual property among pharmaceutical and big agribusiness firms.[100] The strength of the proprietary culture in biotechnology varies from one sector of the industry and from one country to another (the United States often being reported as the most proprietary) but can be extreme:

> There are limited [collaborations among pharmaceutical companies] in different therapeutic areas, but for the most part they compete rather than collaborate... . In the areas I've been involved in, we are barely able to get the companies to sit down in the same room together. If they do they sometimes want their lawyers there.[101]

[98] Denise Caruso, Open Source Biology workshop.

[99] Michael Tiemann, personal communication.

[100] As a licensing executive from a major agricultural firm commented, "Five years ago everybody would have just said, no way. Because everybody was looking to carve out their own niche. Everything had to be exclusive, that was the way you operated, your whole attempt was to build a fence around that so that nobody can touch it." Anonymous informant, personal communication.

[101] Stan Finkelstein, personal communication.

Pharmaceutical companies are at the most proprietary end of the spectrum:

> Pharma live, breathe and die on patent positions... . Not sharing IP is deeply ingrained. So [there is a] knee-jerk reaction... with pharma.[102]

This proprietary culture is reinforced by the inertia of decision-making in a big organisation and by the participation of lawyers and other professionals who are trained and often self-selected to be highly conservative, conditions that exist in both medical and agricultural biotechnology:

> [W]hen you are dealing with a company the size of this one, it's not just me as the licensing manager that makes the decision – I can recommend it, and it can even be a decision that on this site we are comfortable with, but being part of something larger, like most of these companies are, you have to run it by other people because you are basically looking to give up materials that I don't own and the president of this company doesn't own – it is owned somewhere else. [Open source-style licensing would be] a little bit iffy in the way that I have been trained, only because you are giving away something that you don't know quite what it is yet, and that tends to make the higher levels nervous... .[103]

Of course, similar problems exist in software:

> I met a lawyer in a big technology company who had had no exposure to free software, and she is marking up our assignment agreement for the first time as her firm tries to assign some free software. She sent me an email last night saying "Well, I've just tightened up the patent clauses a little, and the clause now says we only transfer patent rights to use and not to distribute and not in combination with any software or hardware other than the software –". And I wrote and said you don't get it, it is wrong, because the whole point is being undermined. But of course she is trained to think in a completely different way and she can't get out of it.[104]

The proprietary culture of large firms is likely to affect the outcome of the proprietary versus free revealing trade-off for other players in the biotechnology industry. Small firms are less likely to be able to license technology to large firms if they cannot guarantee exclusivity, and as we saw in chapters 4 and 5, any kind of collaborative technology development has the potential to create problems in this regard. For small firms, the signalling value of intellectual property must also be taken into account (although this is not necessarily incompatible with free revealing):

[102] Lee Bendeckgey, personal communication.

[103] Anonymous informant (licensing manager, major agricultural biotechnology firm), personal communication.

[104] Eben Moglen, personal communication.

> Basically no biotech companies make any money, so they all rely to a great extent on capital markets... . [I]f investors don't see current profits what they want is a story that explains how you will get future profits and how you won't get bulldozed by bigger, better funded competitors, so patent positions and barriers to entry are important stories for biotech companies to tell investors.[105]

On the other hand, pharmaceutical companies might be very willing to "suck up" freely revealed innovations generated upstream, and it might be possible for smaller firms to attract funding on that basis, just as the TSC research institutions have obtained funding for their research:

> [A]nother way you could think about it would be not so much pharma being the ones who would contribute to the technology, but if you could get them to essentially sign on as potential customers for the technology, then even to the most venal western capitalist that looks like a really good short term customer: we know they have the dollars to pay for it.[106]

However, in order to make this strategy work, a smaller company with a free revealing strategy might need to overcome some suspicion from larger firms unfamiliar with open source-style business models:

> Pharmaceutical companies are big and they like to rely on other big companies for their infrastructure, not on some little twenty-person company. The whole thing in software where people are distrustful of Linux because it wasn't developed within a big firm – pharma would be even more suspicous.[107]

> If you say "We are working with an open source model", people will say, "So what is *that* exactly?" ... You need quite visionary people to think out of the box, so [we would prefer initially] to do a bit of business in more standard terms and then to move on and educate as we go... .[108]

Like smaller biotechnology companies, academic and public sector researchers and their institutions are affected by the traditional proprietary culture within the industry.[109] Unsurprisingly, the strength of proprietary culture within biotechnology research communities tends to depend on the prospects for commercialisation:

---

[105]Lee Bendeckgey, personal communication.

[106]Ibid.

[107]Ibid.

[108]Anonymous informant (senior executive, small plant biotechnology firm), personal communication.

[109]Cf Hilgarter's point (section 2.4, p.14) that different patterns of access subsist within different scientific subcultures.

> [T]he fly [genome] map was a mess, the people who did the YACs were in competition with the people who did the cosmids, everybody was competing with everybody else, it was hopeless. To go into this Coliseum of gladiators was out of the question. ... In the worm community these issues have seldom arisen. No fortunes were riding on worm genes, so everyone (more or less) was happy that information should be shared.
>
> [W]ith the human genome it was a different story. The Sanger Centre began life in an environment in which commercial pressure was always going to be part of the picture. Those who were working to map particular human genes either expected to secure patents on them, or were terrified that someone else would beat them to it. It made for an atmosphere of mutual suspicion.[110]

Although proprietary traditions are likely to be influential, the outcome of the proprietary versus non-proprietary trade-off is not a foregone conclusion, even for pharmaceutical companies, and even with respect to drugs. According to Stephen Maurer, pharmaceutical companies' involvement in the development of the Salk polio vaccine in the early 1950s is instructive.[111] The vaccine as developed by Jonas Salk in 1953 at the University of Pittsburgh did not meet the novelty requirement under patent law, so it was in the public domain. The university did not have the capacity to generate enough vaccine for a large-scale field trial, essential to ascertain both the safety and effectiveness of the vaccine and the best protocol for large-scale manufacture, so it sought the help of several large pharmaceutical companies. The companies knew that getting the vaccine through the next stage of development was going to require substantial investment, would be technically difficult and complex, and entailed substantial risk (in that it was uncertain whether a vaccine would ever be approved). On the other hand, if it could get past the field trial stage, the vaccine would be very profitable because the degree of public fear of polio would ensure all parents would want their children vaccinated. This high risk, high pay-off scenario is exactly the situation in which advocates of a proprietary approach normally argue there is an incentive problem that must be solved by granting patent rights. However, the pharmaceutical companies in this case were willing to make their investment without a patent and even without any exclusive contract to produce field trial vaccine. The reason was that, given the size of the "pie", the lead-time advantage in being ready to move the moment the vaccine was approved was considered worth the risk.[112]

Given a predisposition to taking a proprietary approach, other factors that would be likely to affect the free revealing trade-off would include the current economic climate (which affects pressure on research and development budgets and therefore increases the attractiveness of a free revealing approach, while at

[110]Sulston & Ferry (2002), p.69 and p.111.
[111]Stephen Maurer, personal communication.
[112]Smith (1990).

the same time exacerbating conservative tendencies), how soon the pay-off (for example, in terms of improvements to the technology) is likely to be realised and how large it will be. In the software context, it has been observed that even if a free revealing approach promises to positively affect a company's bottom line, it may not be adopted unless and until there is no other option for that company:

> Just the fact that Linux is ten times cheaper than proprietary UNIX – you'd think that in a competitive world that would be enough. But it's not enough. "What about risks", and "I really like how my vendor takes care of me" and a whole bunch of other reasons mean that a ten to one difference in cost does not guarantee success in the marketplace. ...Most people don't operate based on what is optimal. They operate based on whether this will kill me to do it or whether it will kill me not to do it.[113]

6.3.3 Summary

In summary, although there does appear to be a cultural difference between software (and other industries) and biotechnology (especially pharmaceuticals) with respect to the attractiveness of a free revealing strategy,[114] a number of industry participants can clearly see "spaces or business models that would allow a company to derive an income without chasing intellectual property rights".[115] The examples cited in this section illustrate that free revealing as an exploitation strategy for self-interested innovators is viable in the biotechnology context under appropriate conditions; thus, we are well on the way to establishing that an open source approach to technology development could be implemented in the biotechnology context.

6.4 Collective invention

6.4.1 What is collective invention?

The third element in a user innovation literature-derived model of open source development is collective invention based on free revealing. When an innovator decides to adopt a free revealing strategy in relation to an innovation, the innovation becomes available to other users. Some may take up the opportunity to replicate and use the innovation. Others may go a step further and improve upon it: as with the original innovation, follow-on innovation may take place in response to incentives related to benefits expected to be derived from either from the innovation itself or from the innovative activity, or may take place "anyway"

[113] Michael Tiemann, personal communication.

[114] "In high technology, the attitude towards IP ranges from thinking it's an obstacle to simply ignoring it; for [the biotechnology industry], the knee-jerk reaction goes the other way": Lee Bendeckgey, personal communication.

[115] Stephen Maurer, personal communication.

as a side effect of other activities. Once a follow-on innovation has come into existence, the innovator will be faced with essentially the same set of exploitation options as the original innovator and must undertake the same consideration of costs and benefits associated with proprietary and non-proprietary strategies. If enough follow-on innovators find that the outcome of this trade-off favours free revealing, a cycle of collective invention may emerge in which a series of incremental improvements to a technology are freely revealed and trigger new rounds of innovation.[116] In Hilgartner's terms, the result is a non-proprietary data-stream. Note that it is not necessary for every innovation in each round to be freely revealed: just as river water can be diverted to irrigate surrounding farmland provided diversions remain below the threshold needed to sustain the health of the river system as a whole, a collectively produced data-stream can sustain both proprietary and non-proprietary uses at a range of points along its course, provided proprietary diversions (those that use the resource without replacing it) do not "dry up" the supply for downstream users.

As we saw in chapters 4 and 5, copyleft-style open source licences make use of intellectual property protection – conventionally used, a key element in proprietary exploitation strategies – to establish and maintain cycles of collective invention, or non-proprietary data-streams, in software development by constraining follow-on innovators to adopt a free revealing strategy. Other examples of collective invention documented in the user innovation literature include the development of the Cornish pumping engine during the British industrial revolution,[117] the development of mass production steel in the United States in the mid- to late-1800s, and the early development of personal computers.[118] A further example is the current development of "open source" kitesurfing (a cross between windsurfing and hang-gliding) equipment by amateur enthusiasts and small sports equipment manufacturers.[119]

6.4.2 Conditions favouring collective invention

The literature identifies several conditions that favour the development of a collective invention regime in any given industry.[120] The first condition is that a technological change or other new opportunity may result in a shift in the locus of competition, leading to sharing in relation to the newly non-competitive knowledge, which may create institutions whereby other knowledge is more likely to be shared. The second condition is that there exists a degree of technological standardisation sufficient to facilitate the exchange of information among potential innovators. These conditions are both fulfilled in relation to many aspects of contemporary biotechnology research and development. For instance, con-

[116]Meyer (2003); Nuvolari (2001).
[117]Nuvolari (2001).
[118]Meyer (2003).
[119]Saul Griffiths, personal communication; Zero Prestige kite-building weblog, http://www.zeroprestige.org, last accessed 18 December 2004.
[120]Meyer (2003).

sider the sequencing of the human genome, completed in 2001 by public sector researchers working in fierce competition with the private sector: in this case the free revealing of sequence data, together with changes in United States Patent and Trademarks Office guidelines on the utility requirement for gene patents, shifted competition away from obtaining straight sequence information and towards the large-scale exploration of gene function. As a result, new collaborative initiatives have arisen in the field of functional genomics, creating relationships among institutions and researchers that may facilitate further collective invention.[121] The same technological change has brought about increased standardisation in the industry, in that the genome sequence itself constitutes a common technical platform that facilitates ongoing collaborative research and development. For example, Alfred Gilman, Nobel Prizewinning biochemist and one of the leaders of the Alliance for Cellular Signaling, a multidisciplinary, multi-institutional consortium to study cellular signalling systems, funded from both public and private sources,[122] describes the human genome sequence (together with the Internet: see next section) as a "key enabling tool for the whole project".[123] Note that the cyclical nature of collective invention means that both the shift of competition away from enabling technologies and increasing standardisation are not only causes but also effects of this phenomenon; for example, both are regarded by participants in open source development as desirable outcomes of the open source approach (see chapter 7, sections 7.3 and 7.3.5). More broadly, in relation to standardisation of tools in the biotechnology industry, it has been observed that standardisation of tools has been less necessary in biotechnology than in other industries, including software, because – despite the term "genetic engineering" – biotechnology as it is now practised is not really an engineering discipline in the sense of requiring a common man-made technical platform in order to proceed.[124] This observation ties in with an interesting theme that emerges from discussions about open source biotechnology concerning the boundaries and tensions between science and engineering and between data-driven and theory-driven research, discussed further below. However, there are instances, aside from "natural" standards such as the human genome, where standardisation has been important in the biotechnology industry. For example, in 2001, Incyte Genomics Inc. and Secant Technologies Inc. formed Acero Inc. to market and update Incyte's "Genomics Knowledge Platform", a database tool designed to assist in drug discovery by constructing an interface that allows users to search a number of incompatible databases as if they were part of a unified whole.[125]

The third condition that favours the development of a collective invention

[121] See generally Sulston & Ferry (2002).

[122] Anonymous (2002); Alliance for Cellular Signaling, http://www.signaling-gateway.org, last accessed 28 November 2004.

[123] Alfred Gilman, personal communication.

[124] Tom Knight, personal communication.

[125] IntelligentKM News Service, April 17, 2002, "Vendors Partner on Life Sciences Knowledge Platform", http://www.intelligentkm.com/news/newsapr02.shtml, last accessed 24 July 2003. See also Maurer's discussion of the failed Mutations Database Initiative in Maurer (2001).

regime is technological uncertainty regarding the newly adaptable invention. Technological uncertainty refers to a situation in which the nature of potential products, production processes and markets is either not clear or not commonly understood; it is often accompanied by heavy investment in research and development, leading to low profits in the industry overall, and by income inequality or profit inequality among industry participants such that some firms are wiped out while others grow rapidly.[126] In these circumstances collaborative technology development, as we saw in the previous section (section 6.3), is a means of sharing costs and risks. The fact that high costs in research and development make collective invention more likely is interesting, because one of the apparent obstacles to translating an open source approach from the software to the biotechnology context is that biotechnology research and development – in general – is significantly more capital intensive; by this analysis, high costs may cut both ways. In this context, a corporate attorney for an established biotechnology firm emphasised the distinction between sharing of innovations whose main value is as an intermediate good and those that are valuable as final goods:

> With research tools [the high cost of development as a barrier to innovation] has no relevance at all, and in fact from a pharmaceuticals standpoint, research tools are just an expense, an overhead that doesn't provide any competitive advantage, arguably in the same way that the operating system of all of these boxes, or the Apache webserver – I think it's really quite analogous in that way, once you focus on the customers for open source in software and high-tech and think about the pharmaceutical companies not sharing the *results* of their R&D, but sharing the tools and technologies they use to do their R&D – especially now when they are under such pressure to cut expenses.[127]

As Arrow observed in his essay "Economic Welfare and the Allocation of Resources to Invention", information used as a tool for producing further information will tend to be undervalued by the market because of uncertainty.[128] An open source approach allows the full value of such information to be realised.

The condition of technological uncertainty is certainly fulifIled in relation to contemporary biotechnology; in fact, it is the driving force behind existing extensive collaboration in the industry – as one director of corporate development at a large pharmaceutical firm has observed, "No emerging or established pharmaceutical company is large enough or smart enough to meet all of its knowledge needs in isolation."[129] Chris DeBresson and Fernand Amesse characterise the networks of innovators whose formation accompanied the biotechnology revolution as "relatively loose, informal, implicit, decomposable and recombinable systems

[126]Meyer (2003).
[127]Lee Bendeckgey, personal communication.
[128]Arrow (1962).
[129]Galambos & Sturchio (1998), p.250, note 61.

of interrelationships [that] may start with or encompass a joint venture [or other formal contractual relationship] but go beyond that particular isolated project", and assert that "successful innovation requires setting up a network and the generation of collective knowledge... . [I]n the biotechnology field, an innovative firm cannot exist without its links upstream on the supply side with university research centres and downstream on the demand side with links to hospitals and government regulatory bodies."[130] The distinctive feature of a collective invention regime as an element of a generalised open source model is that participants choose to freely reveal their innovations. While there are many networks of innovation in the biotechnology industry that do not have this feature, some do. Examples in biomedical biotechnology include the Alliance for Cellular Signaling (the Alliance) and the SNP Consortium (TSC), referred to above at p.176 and p.156, respectively. In the case of the Alliance, according to Gilman, the most appropriate description of pharmaceutical companies' motives for participating is "long-sighted self-interest":

> I suppose [the companies, including Aventis, Merck, Johnson & Johnson, Eli Lilly and Novartis] would get some other modest returns in terms of contacts, participation in Alliance meetings, and possibly earlier knowledge of or access to technologies. But because all the participants are committed to communicating openly with the public there is no significant direct advantage to be had by participation, like seeing data before anyone else.[131]

A counterexample from agricultural biotechnology is apomixis research, which involves networks of public and private sector institutions working to achieve asexual production of seeds.[132] Apomixis has been described as "one of the most cherished dreams" of plant breeders, who argue that developing apomictic crops would allow quicker, cheaper production of new varieties of seeds while still allowing farmers to save hybrid seed for the following crop, saving money and keeping yields high.[133] Substantial amounts of both public and private money have been channelled into collaborative projects in which, by contrast with the previous examples, the early dissemination of research results is prohibited, and it is argued that publication delays have led to the collapse of information flows within the scientific community to the point that community newsletters have been discontinued and scientific meetings abandoned. As a result, public research programmes are left in the dark, working on their particular piece of the puzzle, and only the "gene giants" can see the bigger picture.[134] Interestingly, from the perspective of translating the open source model into biotechnology, the

[130]DeBresson & Amesse (1991), p.365ff.
[131]Alfred Gilman, personal communication.
[132]Calzada, Vieille et al. (1996).
[133]GRAIN, "Apomixis: the plant breeders' dream", Seedling, September 2001, available at http://www.grain.org/seedling/?id=20, downloaded 13 November 2004.
[134]Ibid.

reason why attempts to restore and maintain a non-proprietary apomixis data-stream have not succeeded is reportedly that despite the common interest of public sector researchers in overcoming their collective disadvantage, the community has been unable to reverse the breakdown of mutual trust that accompanied entry into proprietary network relationships.[135] Public sector apomixis researchers are now interested in exploring a copyleft-style licensing mechanism that could help them to overcome this problem.[136]

The failure of apomixis research consortia to maintain a healthy data-stream due to excessive proprietary diversions illustrates a point that holds true for networks of innovation and networks in general: perhaps contrary to intuition, it is not the density of internal relationships that sustains the network, but the existence of "weak ties" – distant, unstable relationships – and openness to outside linkages.[137] DeBresson and Amesse note that close-knit clique relationships between partners in a network, while they create resilience in the collaboration, are resistant to change: cliques are typical of cartels and stable oligopolies, not dynamic networks of innovators.[138] Thus, it could be argued that a collective invention regime based on free revealing – which forms a weak tie between information provider and recipient – will be more effective in promoting innovation than a proprietary network characterised by a high proportion of strong ties formed by exclusive proprietary relationships, and therefore more likely to bring superadditive gains to its members. As discussed in the previous section, the opportunity cost of free revealing may be too substantial for prospective network members in biotechnology to embrace this approach. However, another feature of innovation networks highlighted by DeBresson and Amesse is worth taking into account. Geographically localised networks are reinforced by personal, cultural and symbolic networks; it may even be that most external factors that reinforce and help maintain networks of innovators are associated with geographical proximity of network members.[139] In a global industry characterised by intense national and regional competition, it may make sense for biotechnology firms and other industry participants in a local area to engage in free revealing in order to establish a collective invention regime that builds local innovative capacity relative to competitors in other locations: although the innovations would be available to non-local competitors, they would be unlikely to be able to build on those innovations as effectively as firms in the local area.

6.4.3 Summary

In summary, collective invention, once the norm in academic institutions in which the foundational technologies of the biotechnology revolution were developed, has been largely replaced in both public and private sectors by complex propri-

[135] Andrzej Kilian, personal communication.
[136] Charles Spillane, telephone communication.
[137] Granovetter (1973) ; see generally Buchanan (2002).
[138] DeBresson & Amesse (1991), p.368.
[139] DeBresson & Amesse (1991), p.374.

etary networks that combine traditional industry-researcher relationships with new contractual ties involving small biotechnology firms.[140] Some non-proprietary data-streams derived from established collective invention regimes persist, but more interestingly, there is also evidence of new collective invention regimes forming under favourable conditions within the industry, indicating that this element of a generalised open source development model could be reproduced in the biotechnology context.

6.5 Peer production

Given the existence of a collective invention regime constituted by a network of free revealing user innovators, the user innovation literature distinguishes between networks in which users depend on manufacturers to produce working versions of their innovations and those in which the means of production are within the reach of users themselves. A network of innovative users that is independent of manufacturers is termed a "horizontal user innovation network". Open source software development projects are of this type.

6.5.1 Commons-based peer production

The concept of a horizontal user innovation network is closely related to that of "commons-based peer production", proposed by Benkler in his article "Coase's Penguin" (see chapter 4, p.74) as a newly emerging mode of production in which groups of individuals collaborate on large-scale projects following a diverse range of motivational drives and social signals, rather than either market prices or managerial commands.[141] Benkler's analysis is introduced at this point as an illuminating complement to the elements of a user innovation model of open source software development discussed in the rest of this chapter and the next. Like the user innovation model, the peer production model is useful in assessing the feasibility of translating open source development principles into the biotechnology context because it describes open source development in general terms that may be applied outside the specific circumstances of software development.

Benkler identifies a number of cases of commons based peer production, including free and open source software development and traditional scientific research. While acknowledging that peer production is nothing new, he argues that computer networks are bringing about a change in the scope, scale and efficacy of peer production such that it can be applied to larger and more complex tasks.[142] Benkler identifies three components in the chain of information production – generation of content, accreditation and determination of relevance, and distribution – and gives examples of how each component is being produced on the Internet, using a peer based model, with respect to information and cultural goods other

[140] Galambos & Sturchio (1998).
[141] Benkler (2002), pp.371-2.
[142] Ibid., p.383.

than software.[143] From these examples he attempts to abstract some general observations about peer production, including ways in which peer production systems overcome the collective action problems usually solved in managerial and market based systems by property, contract and managerial commands.[144] Benkler perceives two primary problems: providing the necessary motivation for participants and integrating contributions into a useful product.[145] He suggests these will be solved when projects have the characteristics of modularity, granularity and low-cost integration.[146]

Modularity means that the project is divisible into components that can be independently produced such that production can be "incremental and asynchronous, pooling the efforts of different people, with different capacities, who are available at different times".[147] *Granularity* means that modules are "predominantly fine-grained or small in size", yet heterogeneous so that the project can accommodate variously sized contributions.[148] *Integration* entails both quality control and integration of contributions into a finished product; if the cost of these functions is too high, Benkler argues, then either integration will fail or the integrator will seek to appropriate the residual value of the common project, leading to the dissipation of motivations to contribute *ex ante* (but see section 6.5.2, p.185, below).[149]

Recall from chapter 5 that, while not suggesting that peer production will replace market- or firm-based production or that it is always more efficient, Benkler argues that commons-based peer production has advantages over these other two modes in some circumstances (see section 5.4.2, p.106)[150]. The advantages of peer production relative to other modes of production are widely recognised in relation to scientific research. For example, recall from chapter 2 (section 2.7, p.25) that sociologists of science have long argued that the most efficient possible means of co-ordinating scientific research is mutual adjustment of multiple independent initiatives by scientists in light of their awareness of each other's work. In the biotechnology context, early concerns about the commercialisation of university research were sometimes expressed in terms of a conflict between this traditional scientific norm of "individualism" and the organisation of industry-based research in response to market and managerial signals.[151] As emphasised by recent scholarship in the sociology of science, the image of a world of academic science peopled with independent thinkers who exchange information promptly and candidly and a commercial world peopled by scientists whose research focus is narrowly restricted and who are prevented from communicating

[143]Ibid., p.384; Part I (pp.381-400).
[144]Ibid., p.399.
[145]Ibid., Part III,pp.423-444.
[146]Ibid., pp378-379.
[147]Ibid., p.379
[148]Ibid.
[149]Ibid.
[150]Benkler (2002), p.381.
[151]Eisenberg (1989).

with colleagues outside the firm is overly simplistic.[152] However, to the extent that biotechnology research and development retains some of the characteristics generally attributed to academic science before the advent of commercialisation, it would seem reasonable to assume that the "horizontal innovation network" or "peer production" element of a generalised open source model is inherently feasible in the biotechnology context. Nevertheless, some further exploration of how this element of the open source model might be translated into biotechnology is warranted, for two reasons. First, contemporary Internet-enabled peer production, exemplified by open source software development, represents a new step in the evolution of traditional peer production systems and therefore appears to raise new issues relating especially to the exchange of information and the costs of participation. Second, unlike biotechnology research and development, traditional scientific peer production systems are primarily aimed at producing information about the natural world rather than engineering new products. In the remainder of this chapter, we examine some implications of these observations in light of both user innovation theory and Benkler's peer production analysis.

Benkler suggests that peer production of information is emerging because "the declining price of physical capital involved in information production and the declining price of communications lower the cost of peer production and make human capital the primary economic good involved".[153] It follows that the advantages of the peer production mode relative to other modes become salient when human creativity is a salient component of production. Where the cost of physical capital is the central organising principle of information production – i.e. in a capital intensive model – the trade-off may be different. Where physical capital both for fixation and communication is low cost and widely distributed, and where the primary non-human input (existing information) is itself a public good, the primary remaining scarce resource is human creativity, and it is under these conditions that the relative advantages of peer production in organising that input emerge.[154]

These conditions are most obviously fulfilled where the object of production is information or culture.[155] However, it is not difficult to find instances of Internet-enabled commons-based peer production of goods other than information or cultural goods. For example, innovative kitesurfers exchange design information via the Internet using digital recording equipment and written weblog-style descriptions to document test flights, and scanned hand-drawn diagrams and sewing instructions to convey design information.[156] However, in many such instances the physical capital costs of production are low and innovation-related information can be successfully separated from the actual working version of an innovation so that it is not necessary in order to exchange that information for users to produce physical goods and distribute them through the network. (As Benkler points out,

[152]Hilgartner (1997); and see generally chapter 2, section 2.4.
[153]Benkler (2002), p. 444.
[154]Benkler (2002), p377-378.
[155]Ibid.
[156]Saul Griffiths, personal communication.

distribution of information and cultural goods via the Internet is largely a non-issue because it is cheap and the goods can be accessed by anyone, anywhere.[157]) For example, the tools required to produce new kite designs are easily accessible general purpose items found in many homes and workplaces such as sewing machines, video cameras, scanners and PCs, and the raw materials are relatively cheap to buy (designers exchange information about discount fabric sources) or can be substituted with recycled goods (kite crossbars can be made from an old hockey stick or axe handle).[158] For many other types of physical goods, however, production and distribution involve economies of scale that are best exploited by manufacturers (defined, as we saw earlier, as players who benefit principally from making and selling the innovation to others), so that peer production or horizontal user innovation networks are less likely to emerge.[159]

6.5.2 Biotechnology and peer production

Where does biotechnology research and development fall along this spectrum? Innovative activity in biotechnology is frequently claimed to be extremely capital intensive.[160] Unlike software or other information or cultural goods, much biotechnology research and development is either ultimately aimed at the production of tangible goods (such as drugs or seeds) or relates to information which is embedded in tangible biological materials, or both. This means the capital costs for both fixation and communication can be expected to be higher in biotechnology research and development than they are in software development. This consideration has convinced some observers that open source principles could not be successfully implemented in a biotechnology context.[161] It is therefore desirable to examine it more closely.

Claims that biotechnology research and development is highly capital intensive often conflate the inherent capital costs of fixation and communication with other costs. For example, it has been observed that pharmaceutical companies' estimates of the costs of drug discovery and development may be close to an order of magnitude higher than the costs of conducting the same research and development in a public sector setting.[162] Costs associated with corporate profits or with tactical manoeuvring over intellectual property rights are not inherent in biotechnology research and development, but are attributable to the prevailing mode of production; they therefore cannot constitute an argument against the feasibility of a different mode. Other costs may be independent of whether production is organised in response to market-based, firm-based or other signals, but are still not inherent in the research and development process. For example, the

[157]Benkler (2002), p.396.

[158]Saul Griffiths, personal communication; Zero Prestige kite-building weblog, http://www.zeroprestige.org, last accessed 18 December 2004.

[159]von Hippel (2002).

[160]Open Source Biology workshop.

[161]Burk (2002) (discussion following presentation); Open Source Biology workshop.

[162]John Sulston, personal communication; see also Drahos & Braithwaite (2002), pp.167-168.

costs associated with meeting health, safety and environmental regulations for biotechnology-related innovations are very substantial, but ensuring regulatory compliance is a value that may be added at the distribution stage; high regulatory costs are not necessarily inconsistent with peer production at earlier stages of product development (see below).

Even the inherent capital costs of fixation and communication in biotechnology research and development are contingent on external factors such as the cost of local labour required to produce wet lab infrastructure and inventory (generally higher in developed than in developing countries) and the quality of existing transport and communications infrastructure (generally lower in developing countries).[163] Further, it is necessary to distinguish between absolute costs and incremental costs: for example, the incremental capital cost of ongoing research and development in an established and equipped laboratory may be very low despite high start-up costs. Similarly, established laboratories may sometimes have significant spare capacity that could be harnessed at low cost, just as the SETI@home project harnesses unused CPU cycles to process large volumes of data that would otherwise be very costly to manage.[164]

Once extraneous considerations are removed, how capital intensive is biotechnology related innovation? Clearly, the answer depends on the precise nature of the research and development; even within a particular field costs vary significantly from project to project, not only according to project goals but also according to the specific strategy adopted to achieve those goals. Taking these limitations into account, one way to get a "feel" for the costs of innovation in biotechnology might be to examine the itemised project budgets collected by funding agencies such as the National Institutes of Health. Such an investigation was beyond the scope of the present study, but informal discussions with leaders of large and small projects in biomedical and agricultural biotechnology and with funders of research in developed and developing countries consistently supported two conclusions. First, capital costs of fixation and communication in biotechnology *are* higher than the corresponding costs in software development: these costs are actually very low for biotechnology compared with many other technologies, including computer hardware, but software development is remarkably cheap. Second, capital costs almost always account for a significantly smaller proportion of the total ongoing project budget than labour costs. In Benkler's terms, despite a common assumption that the cost of physical capital is the central organising principle of information production in all areas of biotechnology research and development, human creativity is very much a salient component of production in many areas, given basic infrastructure. (It is a common mistake in discussions of open source biotechnology to compare infrastructure costs in biotechnology with incremental costs in software; open source software development relies heavily on pre-existing infrastructure, including elements at the mundane end of the spectrum in Hilgartner's data-stream analysis such as

[163]John Sulston, personal communication.

[164]Michael Tiemann, personal communication; see also Benkler (2004).

telephone connections and electricity supply as well as more specialised elements such as Internet protocols.) Moreover, the capital costs of both fixation and communication in biotechnology research and development are falling rapidly; if current trends continue, then by some estimates the basic tools needed for molecular biology research may soon be within reach of individual hobbyists in developed countries and farmer collectives in developing countries:

> [C]onsiderable information is already available on how to manipulate and analyse DNA in the kitchen. A recent Scientific American Amateur Scientist column provided instructions for amplifying DNA through the polymerase chain reaction (PCR), and a previous column concerned analysing DNA samples using home-made electrophoresis equipment. The PCR discussion was immediately picked up in a Slashdot.org thread where participants provided tips for improving the yield of PCR. Detailed, technical information can be found in methods manuals, such as Current Protocols in Molecular Biology, which contain instructions on how to perform almost every task needed to perform modern molecular biology, and which are available in most university libraries. More of this information is becoming available online. Many techniques that once required PhD-level knowledge and experience to execute correctly are now performed by undergraduates using kits.... DNA synthesis [is] becoming faster, cheaper, and longer, and it is possible that in ten years specified large stretches of sequence will be generated by dedicated machines. Should this capability be realised, it will move from academic laboratories and large companies to smaller laboratories and businesses, perhaps even ultimately to the home garage and kitchen.[165]

Thus, the advantages of peer production compared with market- or firm-based production should apply in many areas of biotechnology. Presumably, however, there will be areas where the cost of physical capital represents a greater proportion of total costs than human creative input. In such situations peer production may not be appropriate at all; but according to Benkler and the user innovation literature, there are two other possibilities. The first is for networks of innovative users to team up with manufacturers for the final production and distribution stages (Benkler's integration step). As noted earlier, this may create obstacles to motivating participation in earlier stages, but a variety of approaches may be used to prevent defection (see section 6.6.2, p.199, below). A biotechnology-related example of users teaming up with manufacturers at the integration stage is Stephen Maurer's suggestion of an open source drug discovery initiative, reminiscent of both GNU/Linux software development and the SETI@home initiative, in which volunteers scan the malaria genome looking for drug targets that would then be made publicly available.[166] Even if promising candidates could be

[165]Roger Brent, email communication.

[166]Stephen Maurer, personal communication.

identified in this way, someone would still have to pay for wet lab experiments and clinical trials, but Maurer, Arti Rai and Andrej Sali argue that an open source approach would reduce the total costs in three ways. First, it would draw on highly trained volunteer labour; second, sponsors could avoid overpaying R&D costs, which are more difficult to estimate accurately earlier in the process; and third, because the results of the discovery effort would be freely available, any company could manufacture the drug, and the resulting competition would keep down the market price for the completed product.[167]

The second option is to introduce cost-lowering mechanisms to bring the costs of production back within the reach of users. Automated integration and iterative peer production of integration are the primary existing mechanisms for lowering integration costs in the peer production systems surveyed by Benkler in "Coase's Penguin".[168] In the user innovation literature, the emphasis is on "task partitioning" as a solution to high production costs;[169] this concept is central to the development of tool kits for user innovation, described in chapter 7 (section 7.2.2, p.213).

6.6 Community support

6.6.1 Innovative networks and community

We saw in the introduction to this chapter that in the user innovation literature, open source software development is characterised as a horizontal user innovation network that is supported by a community. Earlier sections of the chapter deconstructed the concept of a horizontal user innovation network and considered whether each element could or does exist in the context of biotechnology research and development. We now turn to the role of community – defined as a network of interpersonal ties that provide sociability, support, information, a sense of belonging and a social identity[170] – in the open source development model.

Although they often co-exist, user innovation networks and user communities are independent phenomena. This is an important point because many commentators assume that all of the benefits of an open source approach to technology development are inextricably linked with a specific set of community values and practices that are peculiar to the free and open source software community. In fact, even user innovation networks that conform to the peer production or horizontal model discussed in the previous section need not incorporate the qualities of a user community; conversely, user communities are not always innovative.[171] Nevertheless, community support is an important feature of the open

[167] Maurer et al. (2004).
[168] Benkler (2002), p.379.
[169] von Hippel (1994); Jeppesen & Molin (2003).
[170] Franke & Shah (2002).
[171] For example, brand communities are groups of brand users well known to marketers because

source development model. In this section we consider whether the main functions performed by the open source software community can be translated into a biotechnology context.

One important role of a project leader in the open source software context is to establish and maintain an effective community structure that maximises other users' motivation to contribute to further development. The problem of how to motivate participants in a collaborative development effort without paying for their labour in money terms was touched on in chapter 2 in the discussion of economic justifications for intellectual property rights and is discussed extensively in the collective action literature.[172] Briefly, the collective action model of innovation applies to the provision of public goods (goods that are non-excludable and non-rivalrous). By requiring contributors to relinquish private control of innovations, the collective action model avoids the losses associated with restricted access to knowledge that are characteristic of a private investment model in which the innovator appropriates the results of innovative activity, but at the same time creates a problem: if non-contributors can benefit on equal terms with contributors, how can users be motivated to contribute instead of free riding on others' contributions? A partial solution is to supply monetary or other subsidies to contributors, as in the public funding of scientific research; a pure collective action model relies on the characteristics of community to supply the rest of the necessary incentive to participate.[173] In dealing with this issue, the collective action literature suggests criteria for the success of collective action projects in relation to several aspects of community building: recruitment and retention of participants and leadership and co-ordination of contributions (often dealt with together under the rubric of governance).[174]

Interestingly, empirical research suggests that successful open source software projects do not always meet these criteria. For example, according to the literature, small groups should be most successful at collective action because the members of a small group can better monitor and compare their own and others' contributions and incentives can be more carefully tailored to the individual circumstances of potential contributors. In fact, some successful open source projects involve very large groups of contributors who do not know each other, and may involve no active recruiting of participants beyond posting the project's intended goals and access address on the Internet.[175] The explanation given in the user innovation literature for these discrepancies is that open source development is not in fact a form of collective action, but exemplifies a hybrid model of innovation incorporating elements of both the collective action and the private investment models. Specifically, in an open source context, as in the private in-

they carry out the important functions of sharing brand information, perpetuating the history and culture of a brand, providing assistance to other users and exerting pressure on members to remain loyal.Muniz & O'Guinn (2001).

[172]See Benkler (2002), note 17, citing Ostrom, Rose and others.

[173]von Hippel & von Krogh (2001).

[174]Ibid.

[175]Ibid.

vestment model, private rewards to contributors are stronger than those available to free riders; but those rewards tend to be of a kind normally associated with the collective action rather than the private investment model.[176]

Even though the specific criteria for success stipulated in the collective action literature may not apply in relation to projects that follow this private-collective model, the approach adopted in relation to each aspect of community identified above still affects incentives to contribute. Benkler's concepts of modularity, granularity and low-cost integration, introduced in the previous section, are also useful because they relate directly to the problem of motivating contributions in an open source context. The discussion that follows examines the challenge of building an open source community in biotechnology research and development. This discussion is informed by both Benkler's analysis and the collective action literature categories of recruitment, retention, leadership and co-ordination, but is not structured according to either conceptual framework; instead the focus is on apparent obstacles to implementing open source development principles in biotechnology.

6.6.2 An open source biotechnology community?

The following series of statements synthesises common arguments against the feasibility of open source biotechnology research and development (we deal with these issues in the following paragraphs). The pool of potential contributors to open source projects is much smaller in biotechnology than in software – too small to sustain a successful development effort. There are two reasons for this. First, fewer people have the necessary level of skills and commitment to conduct biotechnology research and development. Second, fewer people have access to the necessary infrastructure and supplies. (In addition to directly limiting the number of potential contributors, these factors tend to tie biotechnology research and development to institutions which would restrict individual employees' freedom to "open source" their innovations.) Potential contributors who are not thus disqualified are not motivated by the same kinds of rewards as contributors to open source software projects. Even if they were, these motivations would not be strong enough to outweigh the higher costs of contributing in biotechnology, which are due not just to the need for more expensive equipment but also to higher costs associated with the exchange of uncodified information and tangible objects, including biological materials. The high costs of information exchange in biotechnology would lead potential contributors – both project leaders (initial innovators) and subsequent contributors (follow-on innovators) – to doubt the prospects for successful co-ordination of contributions; to the extent that incentives to contribute are related to the expectation of access to the results of the collaborative effort, such doubt would dissipate those incentives ex ante. Short of this extreme, potential contributors might believe that the project itself has a good chance of success but decide that the costs of providing or receiving infor-

[176]von Hippel & von Krogh (2001); von Krogh & von Hippel (2003).

mation, and in the case of project leaders the additional costs of setting up and maintaining an adequate communications infrastructure for others to use, would outweigh the benefits for themselves. If incentive problems arise in the software context, they may be overcome through charismatic leadership, but there is no equivalent in the biotechnology sphere. Finally, even if open source biotechnology projects could succeed in generating useful technologies, the high costs of regulatory compliance would make the community dependent on large corporations for production and distribution (as discussed in the previous section), with the associated danger of appropriation and the ex ante disincentive to contribute that this implies; in the software context, community pressure is a key mechanism by which this problem can be solved, but this relies on closer community ties than exist in the biotechnology context.

This statement of apparent obstacles to building an open source biotechnology community prompts the following series of questions. How big a pool of potential contributors is required for successful open source development? What level of skill and commitment must these potential contributors possess? Would individuals be free to contribute despite institutional ties? Are biotechnology researchers motivated by the same kinds of collective action-style rewards as software engineers? How expensive is information exchange among collaborators in biotechnology research and development? Are the qualities needed by open source software project leaders substantially the same as those needed and displayed by successful leaders of biotechnology research and development projects? If an open source biotechnology community needed to team up with external players to disseminate the outcomes of research and development, how would it safeguard itself from technology hijacking? There is not room in this thesis for an exhaustive discussion of all of these questions, but each can be answered such that the possibility of success for open source biotechnology remains open. The observations below are offered not as a complete answer to all objections but to give an impression of the kinds of considerations that would need to be taken into account before the feasibility of open source biotechnology could be reasonably excluded.

Size of the talent pool

It is often assumed that the number of potential recruits to an open source biotechnology project needs to be very large for it to have any prospect of success. The underlying reason for this assumption is probably that the best known open source software project, the GNU-Linux development project, involves thousands of contributors drawn from a pool of potential contributors that is assumed to be at least an order of magnitude greater in size.[177] There is, however, no available evidence concerning the ratio of potential to actual contributors in relation to any given project, and certainly no reason to suppose that the ratio is constant from one project to another or that it necessarily would be the same in biotechnology as

[177] von Krogh et al. (2003).

in software. Further, as we saw in chapter 4, there are wide variations in the size of developer groups in the software context, and many projects are worked on by a mere handful of programmers. The question of whether there is an optimal size for open source software development remains open; it has been suggested that there is a critical size of developer community of approximately thirty to forty people,[178] but anecdotal evidence gathered in the course of this study suggests that a team size of six to twenty people is optimal for open source software development because in a larger team it is too difficult for contributors to "keep track of all the moving parts".[179] According to the same evidence, even large projects tend to be composed of sub-teams of a similar size, with overall goals being defined by programmers who are technically proficient but not deeply involved in the actual coding. Open source software developers react with surprise to the notion that very large numbers of potential contributors would be required in order to implement open source principles in biotechnology:

> I mean look how small biotech companies are. There are only a handful that even have a thousand people. Most are probably fifteen to a hundred and fifty people. The open source world is full of fifteen-person projects; it is reasonably full of hundred-person projects. What that means is that there are completely legitimate and completely potent open source activities out there of the appropriate size. You look at things like BLAST; if you are a proprietary company you are just wasting your time to try to compete with BLAST – and there are a bazillion of those things.[180]

Necessary skill level

Of course, what matters to the success of an open source development effort in terms of recruitment is not sheer numbers of potential contributors, but the existence of highly innovative contributors who can "start the ball rolling".[181] In user innovation terms, these are "lead users"; in the open source literature, Bonaccorsi and Rossi describe a "small but efficacious subgroup" that "establishes a critical mass" of other participants.[182] As noted earlier, one factor that could be expected to influence the number of lead users in biotechnology is the capital cost of biotechnology research and development (infrastructure and supplies costs), discussed in the previous section. Another factor is that the skill level and commitment required to conduct biotechnology research and development appears to be much higher than that required to write software:

> It's harder to build things in biology than it is to write code. It's a great deal harder, and it's slower. You really can't do it part-time; ...

[178] Ibid.
[179] Brian Behlendorf, personal communication.
[180] Michael Tiemann, personal communication.
[181] Brian Behlendorf, personal communication.
[182] Bonaccorsi & Rossi (2003), p.1252.

> the skill level at this point is high. For fluency in nucleic acid manipulations, I'd say the typical person here has had eight years of post-undergraduate education.[183]

By contrast:

> Every 16 year-old in the developed world today has a PC on their desk hooked up to the Internet, and those who are so inclined get into the depths of it and see how it works. So it's the pet hobby of the masses.[184]

One difficulty with this argument is that it tends to play down the amount of skill and training needed to make a real contribution in the software field. According to the authors of an empirical study of community joining and specialisation in open source software innovation, software development is a knowledge-intensive activity that often requires very high levels of domain knowledge, experience, and intensive learning by those contributing to it.[185] On the other hand, to some degree the necessary skills in software can be acquired "on the job" (as we saw earlier, learning through feedback from other developers is one motivation for joining an open source project). The quoted remarks imply that this is not the case in biotechnology. However, even if most biotechnology researchers have in fact had substantial formal training, it is not clear that this kind of training is actually necessary for most research-related tasks:[186]

> [At] the sequencing facility at Whitehead in Boston, they have a large community of Tibetan immigrants running most of the instruments and most of the stuff in the shop. They take a six month course at a local community college, where they learn how to synthesise DNA, to make plasmids, to transform bacteria and extract that DNA and they are doing that on a daily basis.[187]

> [The Sanger Centre] would recruit unskilled people, who would...have no need of academic qualifications. We judged them on school achievements, interview and something by which I set great store: the pipetting test. I showed the candidates how to use a pipette – a hand-held tool for manipulating small volumes of liquid – and invited them to have a go [as] an indication of their manual dexterity.[188]

[183]Roger Brent, Open Source Biology workshop.

[184]Greg Graff, personal communication.

[185]von Krogh et al. (2003).

[186]Nor is it clear that any formal training need necessarily be in a biology-related discipline. In the first "BioBricks" course run at MIT in 2003 (see further discussion below), approximately half of the sixteen students had biology backgrounds; the rest had backgrounds in mechanical or electrical engineering or media arts and sciences: Drew Endy, personal communication.

[187]Robert Carlson, Open Source Biology workshop.

[188]Sulston & Ferry (2002), p.75.

In fact, both software and biotechnology development require a range of skill and commitment levels: in Benkler's terms, both activities have the potential to be sufficiently granular for successful peer production. In practice the degree of both modularity and granularity of biotechnology research depends on the nature of the project. For example, DNA sequencing by the method used in the Human Genome Project is both modular:

> We divided up the job by each starting at the same place on a chromosome and sequencing away from one another in opposite directions. That way we had only one overlap between the labs to worry about per chromosome. If it seemed like one lab had a particular problem covered, then the other left it to them.[189]

and granular:

> [As director of the Sanger Centre] I got used to the idea that people would... come in at the level of routine tasks and learn what they could and then move up as high as they could, but there were also people who were coming for a short period who would pass through, even though they were highly qualified, and be happy to contribute something temporarily.[190]

Other projects, at least as currently constituted, may be insufficiently modular and granular to accommodate an open source development methodology. The qualification is key: some such projects *could* be sufficiently modular and granular if these qualities were incorporated as design principles at the strategic planning stage. To appreciate this point, recall that according to Hilgartner's data stream model (section 2.4, p.14) the underlying reality of scientific research is that of a continuous and evolving flow of scientific production on which scientists and others impose artificial boundaries in order to facilitate scientific exchange as well as for a range of other purposes. The packaging of portions of a data stream proceeds according to conventions which vary from one sub-field to another and are not entirely stable. Thus, the degree of modularity and granularity of a research problem in biotechnology is not inherent but is a matter of construction. (In fact, the data stream model is founded in part on earlier constructivist sociological studies of scientists' efforts to modularise their research so as to enable collaboration within and among firms in the biotechnology industry.[191])

This is not to say that there are no limits to the potential modularity and granularity of biotechnology projects. The range of possible ways to package the elements of a data stream is limited in practice not only by convention but by the nature of the data itself. In the biotechnology context, the complexity of living systems means that an apparently small change to one part of the system often leads to substantial side-effects elsewhere in the system that are inherently unpredictable and often delayed, making them difficult to detect even after the fact:

[189] Ibid., p.78.
[190] John Sulston, personal communication.
[191] Fujimura (1987).

> We can't make a model of [living organisms] that lets you predict what happens when you change things... because biological systems that exist in the natural world are optimised to persist; they are not optimised to be easy to understand, or easily modelled, or to respond in predictable ways. ... And so if you're an engineer looking at biology – screw it, right, that sucks![192]

Nevertheless, at present the modularity and granularity of biotechnology projects are effectively limited not by the inherent non-modularity of biological systems but by the prevailing structure of data streams in biological research. This is a persistent tension in biotechnology: just as living organisms, unlike software, have not been engineered from the ground up for human use, biological data streams have not generally been constructed so as to facilitate biotechnological development (defined as the application of biological systems to solving problems or making products). In this view, biotechnology is an attempt to graft an engineering discipline onto an exploratory science base – an attempt that has not so far been entirely successful. Constructing a truly effective set of biotechnology tools for any given application may ultimately require the complete refactoring of the relevant data stream. This refactoring would introduce abstraction barriers that would allow the behaviour of living systems to be predicted within a specified range of conditions, and at the same time create the modularity and granularity necessary for efficient collaborative research and development according to the open source or any other model. One of the initiators of the MIT "BioBricks" project explains:

> Endy: It's about decoupling design from fabrication. [In a refactored biology] people can do engineering of parts, like protein-DNA interactions. That's a whole level of design. Then people can engineer systems, and then cells that have modular systems in them, and then ensembles of cells, and then multicellular systems. So if somebody gave you a bunch of parts and told you how they behaved you could work entirely at [the first] level; if somebody gave you a bunch of systems and told you what their inputs and outputs were, you could work at [the next] level, but if you only wanted to make parts you could just do that. So it lets you focus on just one piece of an insanely complex problem: ... there are layers and layers and if you can separate them from each other then different people can specialise in different layers and you will get a lot more happening.
> Hope: But physically you haven't changed anything?
> Endy: We've changed how we describe the system, and that imposes a new set of constraints on how things can be constructed and it introduces new possibilities too.[193]

[192] Drew Endy, personal communication.
[193] Drew Endy, personal communication.

According to this analysis, the problem with intellectual property rights in biotechnology related innovations – which, as Hilgartner points out, involve plucking items from a continuous data stream and attempting to place them into discrete categories – is that proprietary restrictions designed to facilitate one set of technical goals create barriers to the reconstruction of the data stream to meet another set of goals. In some sense, of course, this is merely a restatement of the problems described in chapter 3, but it helps to make the point that (as with the issue of capital costs discussed in the previous section), any lack of modularity or granularity in biotechnology research is at least in part a consequence of the current conventional approach to intellectual property management and therefore cannot be used as an argument against the inherent feasibility of an open source approach. As we saw in section 6.3.2, above (p.170), the real issue is that uncertainty tends to cause industry participants to view research and development projects through mental filters that screen out all but a few tried and tested ways of partitioning any given data stream.

Freedom to contribute

Returning to our list of apparent obstacles to open source community-building in biotechnology, the next concern is whether, assuming individual researchers have access to the necessary skills and equipment to contribute to an open source development effort, they would be legally free to do so:

> [In biotechnology] you don't have hackers in the same way that you do with software. They're professionals who work within institutions. It's not 16-year-olds sitting there with test tubes in mum's garage; it's people have been acculturated and indoctrinated and have worked up through a system.[194]

Provisions in employment contracts stipulating that intellectual property is to remain the property of the employer might prevent participation, as might the terms of commercial sponsorship or funding agency grants.[195] Despite the stereotype of the hobbyist hacker, this kind of problem also arises in the software context. Some participants in open source software development projects are independent programmers, either amateur or professional, but many are employees whose participation is supported by employers for the sorts of reasons outlined in section 6.3, above.[196] Thus, even if automatic assignment of intellectual property rights is common practice in commercial biotechnology institutions, this may not constitute a barrier to participation by individual employees. In the university sector, restrictive intellectual property policies have been contested by academic staff in many institutions, so that some university researchers may have the right to participate in open source projects without needing permission from the institutional hierarchy; in the software context, at least one major research university

[194]Greg Graff, personal communication.
[195]World Intellectual Property Organization (1992), pp.74-76.
[196]Kim (2003).

has undertaken a review of its policy on contribution to open source projects in response to pressure from researchers.[197] Where permission is required, it can be expected that it will sometimes, but not always, be given as a matter of routine, depending partly on existing incentive and reward structures for technology transfer officers: in universities where technology transfer professionals' own job security depends on maximising licensing revenue from faculty innovations, faculty participation in open source projects may meet with considerable institutional resistance. Clearly, another key factor in the biotechnology context would be whether the university would be expected to meet any of the costs involved in obtaining or maintaining intellectual property protection for open source-licensed innovations. This is not a major consideration in relation to academic employees wishing to contribute to open source software projects, because copyright protection arises automatically; there, the main cost to the institution is the opportunity cost, typically very low. In general, non-profit and for-profit institutions must make the same trade-off of costs and benefits associated with proprietary and non-proprietary exploitation strategies, described above (section 6.3, p.151). Any barriers erected by research institutions to employee participation in open source biotechnology projects might be expected to contribute to the phenomenon described by Eisenberg and others in relation to other proprietary restrictions on scientific exchange, in which scientists engage in unofficial trafficking of resources under the institutional radar (section 3.3.1, p.39). This outcome, reportedly common with respect to open source software projects,[198] would be undesirable for the reasons described in earlier chapters in relation to the problem of tracking ownership in collaboratively generated innovations.

Effectiveness of collective action-style incentives

The next question is whether biotechnology researchers are motivated by the same kinds of rewards as contributors to open source software projects. The answer, briefly, is yes; but the question requires some explanation. This issue is raised as a potential obstacle to implementing an open source approach to biotechnology research and development on the assumption that open source software developers are motivated by ideology or altruism and that biotechnology researchers and their institutions are motivated purely by short term financial self-interest. Abundant empirical evidence demonstrates that neither assumption is justified. Outside observers of the open source phenomenon have been almost obsessive in the search for an explanation of what motivates contributors to open source projects, but this reflects the narrowness of many academic disciplines' understanding of human behaviour, not the radical nature of open source – though open source *is* radical in its potential effects (see chapter 7, section 7.3.5, p.224). Studies in which researchers have actually asked open source project contributors about their motivations show that the main incentive for most contributors

[197]Steven Brenner, personal communication.
[198]Steven Brenner, personal communication.

is the prospect of accessing better technology than they could develop on their own (hence the appeal of the GPL compared with other open source licences).[199] Other motivations described earlier in this chapter in relation to non-proprietary exploitation strategies (section 6.3, above) include process-related benefits associated with the task of coding such as learning and enjoyment[200] and enhancement of private reputations, which can in turn be leveraged for economic gain.[201] Motivations not mentioned earlier (because they relate specifically to the existence of an open source community) include personal identification as an open source developer and perceived indispensability to a team.[202]

None of these motivations are specific to software development, and instances of each can easily be found in the biotechnology context. One of the most striking features of my discussions with biotechnology researchers was that many appeared strongly driven by scientific curiosity, often expressed as a commitment to the scientific enterprise itself, a class of motivation that is related but not identical to the last two categories just mentioned. Some even admitted to motives that sounded suspiciously like altruism.

Of course, responsiveness to collective action-style incentives does not guarantee that the strategic trade-off outlined earlier will result in the decision to contribute to an open source project. It does not even necessarily indicate which way the balance will be tipped by the presence of a particular motivational factor. For example, it might be assumed that the desire to enhance one's private reputation would favour contribution to open source efforts, but this may not always be true:

> [I]n relation to the cathedral and the bazaar... one thing... is how people ultimately get kudos. The thing about cathedrals, of course, is that they tend to have somebody incredibly big and important in charge of them, an archbishop and an arch-architect, and these people gain a lot of prestige. I think there is a worry in science, and I think it is justified, that if you head up something big, even if it is a bit mindless, you get kudos. ... [T]here is no doubt that people do see... their scientific career in this way – "How can I move up and get these accolades?" – and the worry is that in practice, if not in theory, the way to that visible lifetime achievement is through the cathedral. And so people get attracted to the cathedral.[203]

Information diffusion costs

As noted in the list of apparent obstacles to open source biotechnology given above, one major factor that could be expected to influence researchers' decision to participate in an open source project is the perceived cost of exchanging

[199] Hertel et al. (2003) (a survey of contributors to Linux kernel).
[200] Lakhani & von Hippel (2002).
[201] Lerner (2000).
[202] Hertel et al. (2003); O'Mahony (2003); and see generally Brennan & Pettit (2000).
[203] John Sulston, personal communication.

biotechnology-related information. How expensive is it for collaborators in biotechnology research and development to exchange information? In section 6.3.2, p.167, we saw that the incremental cost of exchanging biotechnology-related information that cannot be transferred by Internet can be low if the information is transferred in batches, for example at conferences or during visits to collaborators' facilities. In fact, existing large-scale collaborations in biotechnology such as genome sequencing initiatives or the Alliance for Cellular Signaling make use of a range of mechanisms for exchanging information:

> [A]lmost from the start we began to make the [C. elegans genome] mapping data available electronically over the predecessor of the Internet.... I developed a system of incremental updating, to avoid having to send the whole thing on tape every time. The map was constantly on display. We had regular updates in the Worm Breeders' Gazette, the informal newsletter of the worm community; we showed it at conferences; and anyone could request clones at any time, free, immediately, whatever they wanted, so that they could look for genes. ... Being thousands of miles apart wasn't really a problem. We used e-mail a lot, and [talked] on the phone... . Individual members of the... labs visited each other regularly. The highlight of the year was the annual lab meeting, when we took it in terms to host a visit from all the members of the other lab ... to see at first-hand how the other group was working... .[204]

> Gilman: Communications cost a little bit, but we've found a very economical way to do that via videoconferencing. We can have a spontaneous multisite conference where people can see each other.
> Hope: Is it as good as face-to-face?
> Gilman: Well, it's live; it works pretty darn well. We can see each other and hear each other and swap computer applications, and it actually is quite effective; we do it on Internet 2, which is a university-based, separate Internet. It has zero cost and good traffic – the only real cost is software and... maintenance and operations costs for the equipment. But the Internet is very very important. We couldn't function without the Internet.
> Hope: Does the project involve much exchange that can't be done that way, like swapping samples and materials or mice or whatever?
> Gilman: Yes, a fair bit.
> Hope: Is that a significant cost? – Or are there big delays?
> Gilman: No. I've never even thought about that, it's so far down the list of problems. ... It certainly isn't any kind of hassle: we just ship frozen samples, pieces of cells and so on, by [Federal Express]. The cell laboratory in Dallas is the fountainhead, it starts out with the cells and does incubations with various regulators and does some of the

[204] Sulston & Ferry (2002), p.55 and p.79.

> assays that must be done immediately on live cells, but then the cells are fractionated in various ways and pieces are shipped to Palo Alto or Pasadena or whatever. So: we just freeze 'em and ship 'em.[205]

Regarding the last point, conversations with stallholders at a major international genetics meeting confirmed that a number of companies specialise in shipping biological materials, mainly for clinical trials (which involve bringing materials from many locations to be analysed together in a central location), but also for research purposes.[206] Same-day domestic transportation is standard, with international shipping taking two or three days; the cost is two or three times higher than ordinary postage, but a specialist service offers greater assurance that the samples (including live animals) will reach their destination in good condition and in compliance with regulations (for example, customs and quarantine regulations and regulations concerning clinical trial protocols). At least one such company sponsors regular international seminars on transportation of diagnostic and infectious substances.[207] These details demonstrate that the problems of information exchange are nothing new to the biotechnology industry and that mechanisms already exist for keeping costs (including time delays) to a minimum.

A further point highlighted by the quoted remarks is that sophisticated Internet communications are not the exclusive province of software collaborations. As Porter points out, the Internet is an enabling technology that can be used in almost any industry and as part of almost any strategy.[208] All of the tools available to open source software collaborations for achieving cheap asynchronous communication and for tracking, archiving and searching project-related information are also available to biotechnology researchers, though some tools needed in software development are not needed in biotechnology and vice versa. In this connection it is interesting to note that just as the explosive growth of the Internet was fuelled by the implementation of standard communications protocols, greater standardisation would be enormously useful in establishing large scale open source-style collaborations in biotechnology:

> Hope: In writings about why open source works, one explanation is that all the information involved is digital and can be communicated easily over the Internet. Obviously that has made a big difference, but what about research tools in biology that are not codified in that sense and can't be exchanged instantaneously and for negligible cost: does that rule out the possibility of open source development of those tools, in terms of the costs of communication and of integration of results?
> Bendeckgey: Certainly when you are talking about sharing information, those sorts of things are the first to spring to mind. ...Bioinformatics and data-management aspects of the regulatory process... are

[205] Alfred Gilman, personal communication.
[206] XIX International Congress of Genetics, Melbourne, Australia, July 6-11, 2003.
[207] World Courier, www.worldcourier.com, last accessed 22 December 2004.
[208] Porter (2001).

> the most intuitively obvious places where the application of standards and the flow of data back and forth electronically would lend themselves to an open source approach, but it seems to me that any place in which standardisation would be beneficial – ultimately on some level you are always talking about information, because the technologies are only relevant or useful to a drug company insofar as they generate information about something that could ultimately make a good product. So anywhere you make it easier for things to work together by adopting standards, or adopting standards with regard to technology that make the resulting information more clearly comparable, then all of those are potential areas for an open source approach.[209]

Thus, although the exchange of uncodified information at present does not appear to be costly enough to deter open source-style collaborations in the biotechnology context, greater codification could lead to a whole new range of possibilities. For example, the initiators of the MIT BioBricks project hope to create standardised parts in order to facilitate large-scale collaborative development of engineered biological systems:

> So it's analogous to the beginnings of the Internet, in terms of small groups scattered around the country building their own sets of tools and then standardising them so that they can communicate with each other, and from that small network larger networks building. So we have a timescale, a map of the US, and these are pictures of centres of Internet activity in different cities, and then here are the growing connections between them, and then that spreads to the point where it is recognisable as the Internet. That is basically what we are trying to do.[210]

Governance

The establishment of shared communications protocols is only one of several tasks involved in co-ordinating contributions to an open source project. Co-ordination – which incorporates Benkler's concepts of accreditation and determination of relevance and integration – is one of two aspects of open source governance identified in the open source literature; the other is leadership.[211]

Co-ordination of contributions According to Bonaccorsi and Rossi, effective co-ordination relies on modularity of the good being produced, shared notions of technical validity, established conventions of behaviour and mechanisms for preventing defection as well as a common communications platform.[212]

[209] Lee Bendeckgey, personal communication.
[210] Drew Endy, personal communication.
[211] Bonaccorsi & Rossi (2003).
[212] Ibid., p.1249.

As noted above (p.192), modularity is not an inherent quality of data streams in computer science or biotechnology, but because it keeps the costs of contribution and co-ordination of contributions to a minimum and thus maximises incentives to participate in an open source project, it is considered a matter of best practice in the software context:

> Perens: We try to make it possible for people to make modifications without getting their fingers all over a large piece of code.
> Hope: Would that not normally be part of coding, say if you were writing for your own personal use?
> Perens: It's a good habit in every situation.[213]

In open source software development, modularity is not always explicit or visible even if an ex-post examination of programmer specialisation indicates that it is present.[214] However, the user innovation literature emphasises that clearly delineating different areas of potential contribution is important among large geographically dispersed groups because it lowers the cost for contributors in locating the specific areas where they can contribute and in finding the information and personal contacts they need in order to do so, while at the same time increasing the benefit by raising the visibility of individual contributions.[215] An example of this principle at work in the biotechnology context is the Alliance for Cellular Signaling's attempt to engage the wider signaling community in maintaining "molecule pages" (essentially, web-based interactive literature reviews relating to particular molecules of importance in cellular signaling pathways).[216]

In the software context, shared notions of technical validity are established through fundamental programming conventions; Bonaccorsi and Rossi note that "software itself is a convention or a common language, in which errors are identified and corrected through the mechanism of compilation."[217] The ability to compile source code derived from many sources and run the program to see whether it works is an important feature of open source software development that does not have a direct equivalent in biotechnology. "Compiling to wetware" is not only costly in terms of time and resources – design flaws may take several life cycles of the relevant organism to appear and may be difficult to interpret when they do – but also potentially dangerous in that it generates unpredictable public health and environmental risks. "Dry" or *in silico* experiments are becoming more feasible in some areas of biotechnology, but this option is still limited, both in technological terms and because the systems in question are only partially characterised. Nevertheless, effective quality control – both accreditation and determination of relevance – is crucial to the success of any open source-style development effort, as the following comments indicate:

[213]Bruce Perens, personal communication.
[214]von Krogh et al. (2003).
[215]Ibid.
[216]See http://www.signaling-gateway.org/molecule/, last accessed 22 December 2004.
[217]Bonaccorsi & Rossi (2003), p.1248.

> Paul Rabinow: If you were to ask a high energy physicist how you find out what's going on, it is by logging onto the e-print archives.
> Rob Carlson: I agree with that in principle. The problem is I stopped subscribing because there was so much noise. I had no idea what was good and bad any more.
> Denise Caruso: Are you saying you stopped because it wasn't peer reviewed?
> Carlson: I'm saying that the sheer volume of stuff –
> Caruso: Was it peer reviewed?
> Carlson: No, it's not, but – I mean peer review is important, it separates the wheat from the chaff. But whether or not it's peer reviewed, it is just so easy to send in a paper, and the last time I checked there were thirty different topics you could put as your main heading, and it's maybe sixty by now, and I have no idea how to keep up.[218]

Of course, these issues are not peculiar to open source, but must be dealt with one way or another in any knowledge production system. In academic biology, the traditional quality control mechanism, referred to in the quoted dialogue, is peer review. Much has been written in the sociology of science literature and elsewhere about peer review, but the interesting thing for present purposes is that it is by no means a cheap process:

> Hope: How would you make sure quality control isn't too arduous, such that it would deter people from making contributions?
> Brenner: You can't. Peer review *is* arduous. But because it is tied to reputation, and career advancement and funding, people are prepared to do it. You just have to make the rewards matter.[219]

Thus, the problem of quality control, in biotechnology as in software, boils down to the balance of incentives.[220]

In fact, the high cost of quality control and other tasks involving uncodified biological information compared with software code weighs in favour of an open source (as distinct from proprietary) approach to biotechnology research and development, not against. Even though project leaders can go some way towards establishing the technical validity of information that is to be incorporated into a technology, ultimately the burden needs to be spread as widely as possible:

> Hope: When you say on your website that everything is put out there as soon as it is replicated, is there only one lab that does those replications?
> Gilman: Yes, the San Diego bioinformatics lab.

[218] Open Source Biology Workshop transcript.

[219] Steven Brenner, personal communication.

[220] In the software context, empirical research has shown that the range of motivations is much the same in relation to mundane tasks as it is for high-prestige, "sexy" contributions, and it seems reasonable to expect that this would hold true in biotechnology also. Lakhani & von Hippel (2002).

> Hope: So does replication involve doing all of the experiments again?
> Gilman: Well, we need people to do them enough times that we can be sure we can repeat them and the results are valid statistically.
> Hope: I thought replication normally meant somebody else doing the experiment in a different laboratory, you know, under a variety of conditions.
> Gilman: Well, *we* can't do that. But of course, the information is all out there, so anyone can do it who wants to.[221]

The final requirement for effective co-ordination, according to Bonaccorsi and Rossi, is established conventions of behaviour.[222] As is pointed out in the user innovation literature, technical infrastructure is necessary but not sufficient for the orderly coordination and aggregation of individual contributions over time; social mechanisms are also required.[223] Again, the relevant issues are not unfamiliar in the biotechnology context, and existing large-scale collaborations address them explicitly. For example, in relation to the sequencing of the human genome, John Sulston reports that the most important achievement of the first Bermuda meeting was to "sort out who was doing what" by establishing what he called an "etiquette of sharing": participants "arrived with claims on pieces of paper announcing their intention to sequence a particular region, and during the course of the meeting any competing claims were sorted out."[224] One experienced open source software project leader – Brian Behlendorf, co-founder of the Apache server project – commented that a reasonable standard of behaviour needs to be enforced among collaborative developers: "Some good people have been asked to leave because of poor behaviour. In other cases, people have behaved badly and not been asked to leave, and that has caused difficulties for the project."[225] The same issues arise in biotechnology collaborations:

> Gilman: We really haven't had any big fights yet. ... I guess there are certain people who have not participated to the extent that one would want them to or hoped they would... so there's been some turnover for that reason.
> Hope: So is the approach simply to simply ask those people to drop out and let somebody else take their place?
> Gilman: Yes. The funny thing is that the people who never show up are the ones who are always offended when you say "Hey, you never show up, so no hard feelings but let's call it a day". But it's the steering committee who makes those decisions.[226]

The steering committee referred to is this project's counterpart to the core developer group in an open source software project.

[221] Alfred Gilman, personal communication.
[222] Bonaccorsi & Rossi (2003).
[223] Moon & Sproull (2001).
[224] Sulston & Ferry (2002), p.144.
[225] Brian Behlendorf, personal communication.
[226] Alfred Gilman, personal communication.

Leadership While establishing shared behavioural conventions relates to Bonaccorsi and Rossi's co-ordination aspect of open source community governance, it is clearly closely connected with the other aspect they identify: a widely accepted leadership that sets goals and drives the project forward.[227] Empirical studies show a range of project structures in open source, with different implications for the nature and extent of the leadership role.[228] According to hacker writings, one of the key roles of a project leader is to provide the base intellectual content for the project and continue to seed it with new contributions; experience suggests that cooperative development is most successful if developers can work with an existing body of material.[229] The same is true in the biotechnology context:

> At this point the genome map became truly useful – and the community of worm biologists came into their own. They used the map to find the genes not just as abstract locations but as physical pieces of DNA. With these in hand they could carry out recombinant DNA experiments to find out how the genes worked, study the expression of the genes in different issues, make antibodies to the gene products – all the techniques of modern molecular biology. The genes also helped us by providing new landmarks on the map: it was a virtuous circle.[230]

Another important role for a project leader, according to the hacker literature, is to keep up community morale. This function is important in relation to large-scale collaborations in biotechnology too: as Alfred Gilman has reportedly remarked, there should be "money in the budget for pom-poms".[231] To do this effectively, project leaders need certain social and communication skills – that is, leadership qualities – and this also is true for biotechnology:

> Hope: So in terms of the costs of motivating contributions – how much money *do* you need for pom-poms?
> Gilman: (Laughs.) Ah – well, I think I need a personality transplant, rather than money. ... I could do a better job of cheerleading. I guess I think everybody ought to see the value for themselves of being part of the team, part of the research. ... [But] there are other people in the steering committee who are just eternal optimists, and people like that are certainly very valuable to have around.[232]

Other personal qualities are also important. Open source software leaders often take on an advocacy role; in the biotechnology context, it has been suggested that one of the explanations for the successful establishment of the SNP Consortium was that "the person running it was a CEO, with a CEO look and feel, who was therefore able to do the business in a way that other businesspeople

[227] Bonaccorsi & Rossi (2003), p.1249.
[228] Ibid., p1247.
[229] Behlendorf (1999).
[230] Sulston2002b, p.53.
[231] Thompson (2002).
[232] Alfred Gilman, personal communication.

respected – that a professor, however charismatic, would not have been able to do".[233] The need to maintain credibility with both the academic research community and the commercial sector is thus an important dimension of the required leadership qualities in biotechnology.[234]

Apart from personal qualities, a project leader must be seen to be free of conflicts of interest with respect to the project:

> At one point Affymetrix had this thing they called the GATC consortium and they were basically proposing a standard for micro-arrays...and they had signed up one or two companies to this thing, and the idea was to make the software and different arrays interoperable to make it easier for everyone. Nobody trusted them and it never went anywhere.[235]

> [I]n Bellagio, where we had this declaration about apomixis ... the whole thing built for the first few hours with big interest, then dropped because ...there was a strong personality that was driving this idea and there were immediate questions whether this person did not have too excessive and entrepreneurial an interest in it, and who would be really managing it and how it would happen. So... that was a very unpleasant... outcome: people said OK, someone is going to milk the system for us and I'm certainly not going to put my IP into it... .[236]

This issue relates both to the leadership aspect of governance and the question raised earlier concerning the need to safeguard an open source project from "hijacking" by commercial partners. Because they do not restrict improvements to the licensed technology, open source licences allow "forking" of code development:

> One of the things that happens in the world of software is that people develop software that they think is really wonderful and it gets adopted and it gets used and it becomes popular and there is a developer organisation grows around it, but then the arteries harden. The creativity of the original project slows down. Then someone comes along and says, "You know, I could do that better. I want to fork the development activities and do something different."[237]

Allowing forking gives rise to the possibility that community resources will be spread too thin among many related projects for any of these projects to be successful. It also means that players with market power could fork technology development in a direction that in practice (though not in principle, under a

[233]Roger Brent, Open Source Biology workshop.
[234]Sulston & Ferry (2002), pp.175-176.
[235]Lee Bendeckgey, personal communication.
[236]Anonymous informant: senior executive, small plant biotechnology firm.
[237]Lawrence Rosen, personal communication.

copyleft-style licence) excludes weaker participants. One of the functions commonly ascribed to open source leaders is that strong leadership helps prevent excessive forking by building on personal loyalties. According to Raymond, another important factor is the existence of social norms against forking.[238] Both these mechanisms are community-dependent and some observers therefore doubt they could be replicated in the biotechnology context, where community ties are supposedly weaker than in software.[239] However, discussions with project leaders suggested that while there may be a community dimension to the decision whether to fork a project, the pressure against forking has more to do with pragmatism than with compliance with social norms or contributors' loyalty to a particular project leader:

> It's all about the need to maintain momentum. If you can see a project getting approximately where you want it to go in a reasonable time, you will make substantial compromises in order to avoid diffusing that momentum. If not, you will be inclined to fork it: the decision is just an ordinary business decision about what resources you personally want to contribute in order to get exactly what you want. [240]

Perhaps all these explanations can be resolved by saying that contributors make a pragmatic calculation about what resources are worth devoting to steering a project in a preferred direction, and that the resources involved would sometimes include social capital or political influence. Similar considerations apply in the biotechnology context:

> Some people have come to the project with more specific personal goals in mind, not so much committed to the big picture but to some smaller piece of it, and if that piece changed as a result of a decision about goals and priorities they might lose interest. ... It would be unusual if everyone decided that they wanted to be part of the project for ten years; some people will probably drop out and others will join. It's a floating population.[241]

David Opderbeck has argued that while collective management by way of open source development is appealing, biotechnology lacks the sort of community that would make it feasible; in particular, he says, "the classical and neoclassical story of science as a homogenous, cooperative enterprise that is being corrupted by private property rights does not correspond to reality".[242] In this thesis, I have argued for the feasibility of open source biotechnology from an understanding of scientific activity drawn from constructivist sociological theory – in particular, Stephen Hilgarter's data stream model (section 2.4, p.14) – which

[238] Raymond (2001), chapter 4: "Homesteading the Noosphere".
[239] Opderbeck (2004).
[240] Brian Behlendorf, personal communication.
[241] Alfred Gilman, personal communication.
[242] Opderbeck (2004).

does not rely on such a simplistic narrative. My argument in chapter 5 (section 5.4.4, p.139) for the feasibility of informal enforcement of open source licence terms rested on the assumption that the prospect of losing credibility in future negotiations would deter defection from collaborative development for a sufficient number of industry participants that motivations to contribute would not be adversely affected. However, in a recent paper short-titled "Sharing Nicely",[243] Yochai Benkler goes further. In an analysis based on case studies of distributed computing and carpooling, Benkler demonstrates the existence of sharing practices that "are not limited to tightly knit communities of repeat players who know each other well and interact across many contexts", but are either "utterly impersonal" or take place among "loosely affiliated individuals".[244] This effectively answers Opderbeck's objection.

6.7 Conclusion: open source development in biotechnology

This chapter has taken a generalised model of open source development, drawn from the user innovation literature, and examined each each element of the model to determine whether it could apply in the context of biotechnology research and development. In each case the conclusion is that there is no reason in principle why open source principles could not be implemented in biotechnology. Combining the results of this and the previous chapter on licensing, it is clear that open source biotechnology may be feasible given an appropriate balance of incentives for prospective participants and a determination to work out the details of constructing open source-style licences for biotechnology-related innovations. Given the pre-commercialisation history of biotechnology as an academic discipline developed largely in the public sector, this result is not very surprising; arguably the real question is whether open source biotechnology could go a further step and become a mechanism for reconciling broad access to innovation in biotechnology with economic self-sufficiency, and if so, what effects this might have. This is the subject of the next chapter.

[243] Benkler (2004).
[244] Ibid., pp.275-276.

Chapter 7

Open source biology in action

7.1 Introduction

We saw in chapter 3 that the current structure of the biotechnology industry creates barriers to participation in research and development for those who would stand to gain the most from applications of this powerful new technology. We also saw that the prevalent proprietary approach to exploiting biotechnology-related innovations has been a key factor in generating this industry structure. Chapter 4 pointed out that similar problems have been at least partly overcome in the software context through the evolution of open source as a technology licensing strategy and development methodology. In chapters 5 and 6, we saw that there is no reason in principle why an open source approach could not be implemented in biotechnology. However, we have not yet explored in detail how an open source approach might help to break down barriers to participation in the biotechnology industry; this is the focus of the present chapter.

As we saw in chapter 2, one way to view the recent expansion and strengthening of intellectual property protection in biotechnology is as a consequence of the transition of molecular biology research from an academic environment supported by relatively generous public funding to an environment in which research is expected to fund itself by engaging with the wider economy. In this view the question for researchers and policy makers is how to reconcile for-profit activities necessary to sustain scientific research in the face of declining public support with the need to maintain access to fundamental tools and resources by a diverse range of industry participants.

Studies of bargaining over proprietary research tools in biotechnology show that all current industry participants appreciate the force of the arguments outlined in chapter 2 in favour of sharing resources – they just don't think these arguments should apply to them.[1] That is, most opposition to the removal of access restrictions associated with intellectual property rights is not principled, but pragmatic, and ultimately based on a perception that unrestricted access would conflict with individual players' immediate economic self-interest (whether in maximising shareholders' profits or merely in surviving in an increasingly proprietary environment). Policy makers, influenced by the same perception, hes-

[1] Eisenberg (2001), p.243.

itate to promote unrestricted scientific exchange for fear of the consequences to biotechnology research and development overall if individual firms and institutions were to scale down their participation in order to seek better returns elsewhere.

The open source model provides a radical shift of perspective by challenging the assumption that a restrictive proprietary approach to intellectual property management is always the most profitable. In the sections on free revealing and collective invention in chapter 6 (sections 6.3 and 6.4, beginning p.151 and p.174, respectively) we began to explore the idea that in biotechnology, as in software, the net benefits to an intellectual property owner of a non-proprietary exploitation strategy may sometimes outweigh those associated with a proprietary approach. The first part of this chapter provides a brief taxonomy of open source business strategies that might be implemented in the biotechnology context and identifies some issues that are likely to arise in implementing such a strategy. This section is directed at answering a key question: how to make money from open source? The second part of the chapter takes a longer view of open source strategies, considering how the adoption of an open source approach to intellectual property management by some biotechnology industry participants could have far-reaching effects on industry structure, removing or greatly reducing the barrier to participation by less well-resourced players.

7.2 Implementing an open source strategy

In a healthy competitive industry, businesses must strive to meet consumers' needs. For the reasons given in chapter 6 (section 6.2, p.144) innovation by users is often more successful at meeting consumer needs than innovation by manufacturers. Therefore, mainstream businesses in several industries have sought ways to harness user innovation for their own commercial purposes. As a result, there exist a number of fairly well established mechanisms for capturing benefit from existing user innovation. Ranging from low to high customer involvement in product development, these include conventional market research, providing research and development assistance to users interested in new applications for standard products, supporting custom product groups and user groups, monitoring innovative user communities and identifying and working closely with lead users.

Open source business strategies go a step further, actively promoting user innovation by making technologies available in easily-modified form, at low or no cost, under licensing terms that allow users to make changes to the technology and to use or distribute the resulting modified versions as they see fit. (Note that although the word "business" suggests that these strategies are only useful to commercial players, in fact their use is open to any industry participant seeking to achieve a degree of economic self-sufficiency: we return to this point in the next section.) If successful, this "free revealing" on the part of the technology owner establishes a cycle of collective invention which may enhance the value

of the technology to users in a number of ways. The company or institution that owns the technology then seeks to convert this enhanced use value into economic benefit. Thus, a successful open source business strategy has two components: maximising the use value of the technology, and translating increased use value into economic value for the technology owner.

7.2.1 Maximising use value through open source development

A number of factors contribute to the use value of any technology. For example, the value of a tool to its user is often higher if the user understands how the tool works. In biotechnology, such understanding is often incomplete because many biotechnology tools were not designed from scratch by humans but incorporate complex living systems as components of the technology. Providing access to the technology in its preferred form for modification may allow users to interpret unpredictable results with greater confidence and to imagine new uses that might not have occurred to the technology owner.

The use value of a technology also depends on its quality. The overall quality of a tool depends on its accuracy, reliability, versatility (or, conversely, its suitability for a specific job), interoperability with other tools and robustness to changes in the use environment. The open source approach of involving a large number of users in the development of a research tool contributes to quality improvements in two ways. First, a large group of users can eliminate design flaws and introduce enhancements more rapidly than an in-house product development team: in Eric Raymond's dictum, "given enough eyes, all bugs are shallow". (This is an affirmation of the polycentric approach to research and development discussed in chapter 2, p.25.) Second, the existence of a development community that includes both users and owners of the tool allows users to communicate needs and priorities to owners so that overall development efforts are more likely to be directed towards the most useful tasks.

The use value of a technology also depends, ultimately, on its accessibility. Accessibility is a function of availability and affordability; both are enhanced if a technology can be obtained from more than one supplier. Open source licence terms increase the likelihood that this will be so by ensuring free redistribution by any licensee; the same licence term enhances the accessibility of the technology in terms of freedom to operate by ensuring freedom from legal encumbrances (with the possible exception of a copyleft reach-through term).

7.2.2 Translating increased use value into economic benefit

Assuming that a technology owner's free revealing strategy has been successful in inducing follow-on innovation with respect to the technology, there are a number of possible strategies for turning the improved use value of the tool to the owner's economic advantage. Which strategies are most likely to be applicable depends on the owner's relationship to the tool (in user innovation terms, its "functional class"). Companies or other institutions (such as universities and

public or private non-profit research institutions) that use a particular research tool as a core component of their business process or research program would benefit directly from any improvement in the use value of the tool. For example, large firms may conduct in-house gene sequencing even though such a service is not part of their commercial offering; a further example would be if pharmaceutical companies were to open source their chemical libraries (libraries of small organic molecules used as chemical probes to validate drug targets) or related technologies, for example methods of synthesising molecules, assays for protein types, instrumentation for high-throughput measurement of biological assays, or data sets and analysis methods for predicting toxicological and other properties of selected molecules.[2] Other examples were given in the free revealing section of chapter 6. Non-user technology owners, for whom the technology is valuable primarily as a product rather than a tool, would need to employ a different strategy.

Several strategies have emerged in the software world for generating increased revenue by enhancing the value of a technology to users through open source development. These are discussed extensively in informal "hacker" literature and in at least one dedicated Internet discussion group.[3] The most important single point to emerge from this discussion is that deciding whether to implement an open source strategy requires a careful assessment of one's overall business or strategic plan. Essentially what is needed is to identify and weigh up all revenue-generating opportunities, proprietary and non-proprietary, in order to determine where the firm or institution's true proprietary value lies. Everything outside the inner circle of protected ideas and technology is available for instigating external innovation from which the organisation can derive benefit;[4] in some cases the trade-off may be between the strengths of different intellectual property assets, for example, patents versus trademarks.[5]

One essay that has been influential in the informal literature on open source business strategies is Frank Hecker's "Setting up shop: the business of open source software",[6] which identifies eight distinct open source business models in addition to the direct user model referred to above. (Others prefer the term "business strategy" to "business model" because open source strategies may be used in combination with each other or with proprietary strategies within a single business model.)[7] These may be classified as follows.

[2]NIH, "Roadmap for Molecular Libraries", http://nihroadmap.nih.gov/pdf/NIHRoadmap-MolecularLibraries.pdf, last accessed 22 December 2004.

[3]See, for example, Behlendorf (1999); Young (1999); Tiemann (1999); Hecker (2000); Initiative (2002); and many other papers at Free/Open Source Research Community online papers collection, http://opensource.mit.edu/online_papers.php, last accessed 22 December 2004. Internet discussion forum: Lawrence Rosen, personal communication.

[4]Gabriel & Goldman (2004).

[5]James (2003), p.74.

[6]Hecker (2000).

[7]Brian Behlendorf, personal communication. This is consistent with the real-world application of these strategies in the open source software context; for example, the Red Hat business model incorporates up to twenty different revenue streams: Webbink (2003), p.5.

Exploiting complementary markets

Hecker's "widget frosting" and "service enabler" models rely on leveraging the improved use value of an open source technology to enhance the appeal of a complementary product. ("Widget frosting" refers to a model in which the primary revenue is generated by the sale of tangible goods (widgets), while in the "service enabler" model, the complementary product is a service.) In either case, the quality of the open source technology is important to the value of the overall product, but because it is not a direct source of competitive advantage, it makes sense to spread the cost and risk associated with its development. An example of this approach in the biotechnology context would be if a manufacturer of microarray readers were to give away instructions for spotting microarrays in order to sell more readers: the fact that the information would be freely available would mean that overall use of arrays would increase.[8] In fact, use of the software version of this strategy, in which a company primarily in business to sell hardware distributes enabling software such as driver and interface code at no charge along with the hardware, is also fairly common in the biotechnology context, where the hardware might be sequencers, centrifuges or a fluorescence activated cell sorter and the data analysis software is open source. IBM, a major user of the complementary markets strategy in the software context, is now supporting life sciences technology development because the company can see that, ultimately, it will sell more hardware if it can help push the computerisation of biology: the hardware is more valuable the better the data and the better the tools for manipulating the data.[9]

Providing services

Hecker's "support seller" and "accessorising" models are essentially service models. In the support seller model, the technology is distributed on an open source basis in order to grow the market for the technology itself and associated offerings. Revenue is generated by selling the technology in a form that is easier or more convenient to use than the freely available version and by providing services such as training, consulting, custom development, and after-sales support or accessories such as user manuals; clearly, successful implementation of this type of business strategy depends on careful pricing. In the software context, the ultimate profitability of a pure service model is still in question, but in the biotechnology field this model is actually more likely to succeed because the stickiness of biotechnological information means that users of a technology are often prepared to pay a premium in order to avoid some of the trouble and expense of optimising a published protocol. An example of this approach in the biotechnology context would be if an assay kit manufacturer made the assay protocol freely available, or

[8] see Pat Brown, Stanford University School of Medicine, "The Brown Lab's complete guide to microarraying for the molecular biologist", http://cmgm.stanford.edu/pbrown/, last accessed 22 December 2004.

[9] Stephen Maurer, personal communication.

the owner of a cell line or other biological material that was particularly difficult to work with made the material itself available on open source terms but then charged a consulting fee to provide advice on how to use it. Again, the software version of this strategy is often used in the biotechnology context in relation to bioinformatics software: if the software itself is open source, a company's competitive advantage might derive from the user interface rather than from the underlying algorithms that analyse DNA chips, protein chips, or sequencing gels. Similarly, in the race between the private company Celera and the public sector initiative to sequence the human genome, it has been suggested that Celera could have given away its genome sequence data and made money by selling genome annotations.[10] Had Celera won the race, the strategy it in fact adopted would have been far more lucractive; but in the event, Celera lost and the company collapsed – an outcome that could have been avoided had it adopted an open source approach.[11]

Market positioning

Hecker's remaining strategies – "loss leader", "sell it, free it", brand licensing and franchising – all relate to market positioning. In the first of these strategies, an open source product is used as a loss leader for technologies commercialised in a more conventional way: that is, the open-source product generates little or no revenue, but helps to build the firm's overall brand and reputation, may add value to conventional products, and increases the number of technology developers and users that are familiar with and loyal to the product line as a whole. The second strategy is similar, except that the product that is open source is not a different technology, but a slightly out of date version of the product that generates the bulk of the revenue. Brand licensing and franchising are common business strategies that are closely related: in the open source context, both involve charging a fee for the right to use brand names and trademarks associated with technology that is itself open source. An example of the "sell it, free it" approach in the biotechnology context would be if an older version of a cell line were licensed on an open source basis in order to increase demand for a newer, improved version; an analogous situation would be if a technology were licensed exclusively for a short period and then under a broad, low cost, non-exclusive licence. In the microarray context (see chapter 6, p.155), an "Affymetrix Inside" logo (analogous to the "Intel Inside" logo) might be a successful branding exercise, even if others were able to make chips using Affymetrix technology.[12] An example of the fran-

[10] John Sulston, personal communication.

[11] A coda to this story, however, is that this might not have been the best outcome from a public interest perspective, because the open source public sector annotation intiative, Ensembl, would then probably not have been established: John Sulston, telephone communication.

[12] "Intel do not make all their own chips, but people that supply those chips to them have to meet certain quality standards and they also get the advantage of innovations that Intel makes in semiconductor chip manufacturing. So in that case, the brand includes a technology element; this would be true in the life sciences sector also, at least for the space occupied by Affymetrix." Thane Kreiner, telephone communication.

chising strategy might be if a genotyping service provider were to open source a genotyping technology and sell franchises and support to other service providers in different areas of the world or working with different crops.[13]

Derivative markets

A further strategy not identified by Hecker would be to open source a technology in order to create or expand a derivative market. An example of this approach would be the strategy described in the user innovation literature as the "tool kit" approach, in which a manufacturer provides a set of design tools to allow users to participate fully in product development within a given "solution space" defined by the parameters of the manufacturer's production process. This approach first emerged in the 1980s in the high technology field of custom integrated circuit design; by 2000, semiconductor manufacturers' sales of user-designed chips were worth $15 billion.[14] Providing tool kits for user innovation is not incompatible with a proprietary approach, and in fact, the components of most existing tool kits are proprietary, so that the manufacturer retains control over innovations produced through their use. However, manufacturers can also capture benefit from user innovation generated through the use of non-proprietary tool kits; developing an effective tool kit is arguably easier if its components are non-proprietary as this eliminates some of the tension between ensuring that tool kit components are readily available to users and enforcing intellectual property restrictions. An interesting example of such a tool kit in biotechnology is the MIT "BioBricks" initiative, discussed in chapter 6, which is intended to emulate the custom chip approach.

The tool kit strategy may be particularly relevant in the biotechnology context because, as we saw in section 6.5.2, p.186, some biotechnologies may be suited to open source development up to the production and distribution phase but then require a more centralised approach, especially where regulatory compliance costs are high. The user innovation literature points out[15] that the introduction of an open source approach into a particular marketplace can create significant first-mover advantages because manufacturers tailor the tool kits they offer to allow easy, error-free translation of designs made by users to their own production capabilities: thus, even if the tool kit language becomes an open standard, the originating firm or other institution will retain a competitive edge. This is not an important feature of open source software tool kits, but to the extent that the means of production in biotechnology remain beyond the reach of ordinary users such that manufacturers are required at the stage of integrating user innovations to create a usable product, it may be an important motivation for some biotechnology firms to offer tool kits. However, the introduction of tool kits can impact existing business models in a field in ways that may not be to manufacturers' advantage in the long run, as customers and independent tool developers

[13] Andrzej Kilian, personal communication.
[14] von Hippel & Katz (2002).
[15] Ibid.

eventually learn to design tool kits that are not tied to the production facilities of a particular manufacturer. Some manufacturers may decide to adopt a tool kit approach anyway in order to obtain the short-term benefits.[16] Alternatively, tool kits may be introduced by non-commercial players as a means of shifting competition in the industry away from fundamental enabling tools. These possibilities are discussed in more detail in the second half of this chapter.

7.2.3 Choosing a licence

One necessary task in implementing an open source strategy is to choose an appropriate open source licence to suit the specific circumstances. A copyleft-style licence would be important for the success of the direct user strategy referred to in the previous section because the aim of such a strategy is to capture external innovation for in-house use; a licence that allowed licensees to distribute modifications to the technology on a proprietary basis would defeat this purpose. For the other strategies mentioned above, the reason for open sourcing the technology is to ensure its widespread use. In this case, a copyleft-style licence may still be attractive as a way of reinforcing motivation to contribute to technology development, but it may sometimes make sense to permit some modifications to be appropriated by others: the question is which approach would create more incentive for contributors. As noted in chapter 5 (section 5.4.4, p.129), in the biotechnology context a further consideration is the cost-effectiveness of obtaining and maintaining intellectual property protection.

7.2.4 Hybrid strategies

A number of businesses and institutions in the biotechnology field have already adopted strategies that are not strictly open source, but either consciously borrow from the open source model or have evolved independently to have some similar features.[17] The foregoing discussion highlighted the possibility of mixing proprietary and non-proprietary strategies in a single overall business model or strategic plan; "hybrid strategies" refers instead to modifying one or more of the essential principles of open source licensing to produce a true proprietary-non-proprietary cross. Hecker analyses the range of possible hybrids in terms of a relaxation of one or more key open source licence terms: source code availability, nondiscrimination among users, and nondiscrimination among types of use.

Source code

Hecker notes that an open source licence grants a number of distinct rights in relation to source code (or in biotechnology, the source code equivalent): the right to view, use, and modify the code and the right to redistribute it in modified or

[16] Franke & Schreier (2002); Jeppesen (2002); von Hippel & Katz (2002).
[17] Hecker (2000).

unmodified form (see above, section 4.4.1, p.77ff). In a hybrid model, any of these rights could be made conditional on payment of ongoing fees. For example, the technology owner might wish to charge a fee for redistribution of modified versions of the technology. In the software context, an example would be Microsoft's Shared Source program (in which users are permitted to view the source code but not to use, modify or redistribute it) or Sun's "Community Source Licence", used to preclude code "forking" and to generate some revenue in exchange for redistribution rights.[18] In the biotechnology context this type of hybrid strategy is frequently adopted in relation to proprietary databases, where unconditional access is provided to basic data but access to extended ways of viewing the data that facilitate comparisons or other manipulations is available only on payment of a licence fee.

The viability of this strategy, as with any of the true open source strategies listed earlier, depends on how it is received by users. Sun's licence, while not approved by the Open Source Initiative as an open source licence, is accepted by many software programmers as a legitimate variation on the open source theme, whereas Microsoft's Shared Source strategy is seen as having very limited use and is generally regarded with suspicion.[19] In the biotechnology context, the disadvantages of limited database access are well recognised within the research community:

> By signing up [to Celera's proprietary genome sequence database], academics agree to download what they need for their own use but not to redistribute the data. This... means that the normal exchanges of bioinformatics are inhibited, can take place only through the company's database and are restricted to subscribers. How many biologists really think that this is a good way to run their research? Not many..., which is why there is general support for continued public sequencing.[20]

Given the danger of alienating users by imposing restrictions on the availability of the source code equivalent in an otherwise open source licence, a company or institution considering such an approach – or any hybrid approach – should ensure that its reasons are commercially sound and do not simply represent a reluctance to depart from a more familiar proprietary strategy. For example, one small biotechnology company I visited during my fieldwork was interested in adopting an open source approach but lacked the confidence to abandon all hope of generating revenue from licence fees; as a result, discussions with potential users of the licensed techology aimed at establishing an active developer community were in danger of being sidetracked by arguments over the exact size of the royalty, which in any case was never intended to be significant. Thus, the success of the whole strategy was jeopardised for the sake of a token amount of

[18] Bill Lard, in Rosen et al. (2003) p.57.
[19] Bruce Perens, personal communication.
[20] Sulston & Ferry (2002), p.261.

licensing revenue.[21]

Users

As we saw in chapters 4 and 5, a true open source licence may not discriminate among users. However, a hybrid strategy might distinguish between commercial and non-commercial users, for example allowing non-commercial users full open source-style freedoms but charging a fee to commercial users. This is a common approach in biotechnology. For example, Celera's sequence database, referred to above (p.215), allowed academic use at no cost but charged a fee for commercial users;[22] Incyte's Global Knowledge Platform initiative would have made a similar distinction. Outside the database context, Stanford University adopted an analogous strategy in relation to its Phoenix cell lines, which were patented for use in the production of a particular drug. The University licensed the patent exclusively to a single firm, but made the cell line itself available to other companies on a non-exclusive basis to be used for research purposes.[23]

Fields of use

An open source licence may not discriminate according to "field of endeavour". However, as discussed in chapter 5, allowing field of use restrictions may be an acceptable modification to the strict open source approach in the biotechnology context. For example, we saw in chapter 5 (section 5.4.2) that field of use restrictions are likely to be an important aspect of PIPRA's licensing practice.[24]

7.2.5 Internal adjustments

After choosing a business strategy and an appropriate licence, the next step for an institution wishing to implement an open source approach is to review its internal incentives structure in order to avoid or overcome resistance to new business practices. This is necessary in any strategy for externalising some aspect of technology development because the design and staffing of any institution's innovation-related activities reflects implicit biases about the source of innovation;[25] significant organisational changes may be required if customers or clients become a major source of innovation. In the case of an open source approach it may also be necessary to find ways of countering proprietary mental models and cultural biases at all levels of the organisation. We have seen in chapter 6 (section 6.3.2) that this is likely to be a serious issue in at least some sectors of the biotechnology industry.

[21] Anonymous informant: senior executive, small plant biotechnology firm, personal communication.

[22] Sulston & Ferry (2002), p.261.

[23] Kathy Ku, personal communication.

[24] See also section 3.5.4, p.59.

[25] von Hippel (1988), p.118.

7.2.6 Disseminating the technology and building a community

A key element in the success of any open source strategy is to evolve the licensed technology continually and rapidly in order to satisfy lead users: in open source software terms, "release early and release often".[26] This is, of course, true for many proprietary tools also, but it is particularly crucial in the case of an open source approach because, as we saw in chapter 5 (section 5.4.4, 132) the quid pro quo for contributing improvements to the common pool for many users will be the expectation of gaining access to leading edge technology. Large-scale collaborative efforts in biotechnology already follow this principle; for example, prompt release of sequence data is mandated under the Human Genome Project's Bermuda protocol.[27]

To evolve a technology sufficiently rapidly to support the business strategies listed above, it is essential to find or build an effective user community; as we saw in chapter 6 (section 6.6), this is an important aspect of the open source model of technology development generally. In the open source software context, commercial operations have not necessarily managed to optimise community involvement; from the company's, and a broader, perspective there is a danger that the community will be swallowed up and its usefulness compromised if it allows itself to become too closely aligned with commercial players.[28] The open source software community has so far successfully resisted co-option by commercial interests; an open source biotechnology community would need to find ways to do the same, especially if it finds itself dependent on sponsorship in the early stages (see discussion of licence development in chapter 5, section 5.3, p.98 and below, section 7.3).

We considered some of the challenges to building an open source community in biotechnology in chapter 6 (section 6.6, p.186). That discussion illustrated certain tensions inherent in achieving a community structure that maximises incentives to contribute to an open source development effort (for example, there is a tension between keeping down the friction costs of contributing and maintaining tight enough organisation to reach project goals within a timeframe that is useful to contributors). Several specific issues have been identified in the user innovation literature in relation to establishing a community to support the rapid evolution of tool kits.[29] First, the solution space of the tool kit – that is, the technical parameters within which open source development is intended to take place – should be clearly defined. Second, it should be easy for users to interact via the Internet or other low-cost rapid communication methods. Third, community web pages should be of a quality that satisfies the immediate needs of casual visitors so that they will return to the site and possibly become new users. Fourth, voluntary user communities are more effective than those established by the tech-

[26] Raymond (2001), chapter 3: "The Cathedral and the Bazaar".

[27] Available at http://www.gene.ucl.ac.uk/hugo/bermuda.htm, last accessed 27 August 2003; see also Marshall (2001); Morgan (2002).

[28] Michael Tiemann, personal communication; Bruce Behlendorf, personal communication.

[29] von Hippel & Katz (2002).

nology owner because the support they offer users is more likely to be directly applicable to the kinds of problems users enounter and because any information they distribute will be perceived to be free of commercial interest. Finally, there are a range of tangible or intangible rewards that may be offered to sustain community participation, including explicit recognition of useful contributions.

7.3 Structural effects of open source in biotechnology

The previous section showed why an open source commercialisation strategy might appeal to an individual profit-making firm or non-profit institution seeking some degree of economic self-sufficiency. In this section we consider the possible consequences of adoption of an open source approach to intellectual property management by even a few players in the biotechnology industry. The progression described in this section is not presented as a prediction of what will happen if some industry participants adopt an open source approach; rather, it is presented as a series of "what-ifs" in order to show how radical a shift might come about given favourable conditions at each stage.

7.3.1 Starting with a usable open source technology

The impact of open source business strategies within a given market segment begins with the development of a usable technology or set of technologies with sufficiently broad appeal to kickstart the diffusion process. We saw in chapter 4 that in the software context, the Free Software Foundation set out to create a full suite of free technologies, from operating system through to applications, as an alternative to proprietary technologies. By analogy, it might be assumed that this is what an open source biotechnology initiative should set out to do. Interestingly, however, the Free Software Foundation has never actually achieved this goal. What it *has* achieved is first, the seed of some useful technologies that other people found interesting enough to develop further, and second, a collection of very useful free development tools that allowed them to do it. It was from this base that the GNU/Linux operating system evolved, essentially the turning point for open source success.

In the biotechnology context over the same twenty year period, development tools *have* been created, and, as with software, this has occurred largely in the public sector. The difference is that certain key biotechnology development tools were then licensed or assigned to corporations on an exclusive basis in all territories and across all fields of use, such that only those corporations were able to use them.[30] Part of the reason was a lack of sophistication on the part of the universities where important tools were developed: in particular, the importance of retaining as many rights as possible to allow broad licensing in service of the universities' public interest missions was not clearly understood.[31] Thus, technolo-

[30] Atkinson et al. (2003).

[31] Greg Graff, personal communication.

gies were developed, but they were tied up in proprietary arrangements instead of being made freely accessible like the free software development tools. Now, however, some United States land grant universities are starting to take stock of what rights they retain, particularly in agricultural biotechnology, and to realise that collectively they are at least as powerful – in terms of their intellectual property holdings, at any rate – as any single player in that industry sector. These universities are considering how to manage their intellectual property in future to avoid indiscriminately alienating important tools and looking at ways to create licensing packages that provide smaller players (for example, Californian walnut growers) with access to a full set of development tools. Part of this process is to identify what is missing from these tool kits so that licensees can be advised as to what other technologies they will need to obtain and so that they can channel their own resources to inventing around (their own) patents and filling those gaps.[32]

Of course, once these gaps are identified, other developers may also contribute to creating a full set of "meta-technologies". Non-profit research institutions might seek funding from governments or philanthropies for this purpose; alternatively or in addition, for-profit companies might do the work, relying on government procurements or capital from oligopolists keen to erode one of their rivals' competitive edge in relation to a give type of tool. Some firms might calcuate that they could make enough income from one of the strategies described earlier to justify licensing their own technologies on terms that are either open source or so low cost that they are still accessible as components of an overall package that is mostly open source.

While it is in theory possible that a full set of open source biotechnology development tools could be put together entirely out of technologies developed by individual firms and non-profit institutions following incentives provided by the open source strategies described above, current discussions of open source are also exploring the role that sponsors might play in bringing together a "meta-tool kit".[33] Such sponsors might be governments, philanthropies, or large corporations – not just pharmaceutical companies or big agribusiness, but firms like IBM who are equipment manufacturers in both software and life sciences and would be interested in open source biotechnology for the same reason they are interested in open source software. The advantage of seeking sponsorship from the latter source would be that the sponsor would already have experience in and understanding of open source principles. A recent initiative of the Centre for Applications of Molecular Biology in International Agriculture (CAMBIA) that is, in fact, sponsored by both IBM and the Rockefeller Foundation is BioForge, an Internet clearinghouse for open source biotechnology development projects analogous to the Sourceforge.net open source software repository. According to its web introduction, BioForge aims "to catalyse a large community of innovators to produce high quality and relevant biological technologies for the empowerment

[32]This is the PIPRA initiative: see Atkinson et al. (2003) and section 3.5.4, p.59.
[33]Open Source Biology workshop.

of diverse problem-solvers in the developed and developing world, and secure these technologies in a new, protected, universally-accessible commons".[34]

7.3.2 Open source creates a competitive challenge

If an open source technology has greater appeal to users than competing proprietary technologies, they will begin to show a preference for the open source technology. Conditions that would favour the diffusion of an open source technology include the following.[35] First, any increasing returns to the adoption of a competing established technology are outweighed by network externalities associated with access to the new technology; the balance will depend on the type of tool. Second, the intrinsic value of the technology is high. Third, revision of technological choices is not too expensive: if there are high fixed costs, users of established technologies will want to avoid changing horses midstream. Fourth, there is a heterogeneous user population – this relates to the mechanism of diffusion through networks of users with a variety of social links. The final condition favouring diffusion of a new technology is weak or absent competitive reactions from industry incumbents, discussed below.

Open technologies are resistant to competitive countermeasures that are available to larger established industry participants, such as buy-outs and undercutting on price: in the software context, it has been said that "today's vendors are facing a competitior that has no stock, no owners, no board of directors – a competitor they cannot buy and cannot attack in a price war because its products already sell for nothing".[36] In biotechnology, if an open source technology is initially dependent on the support of a particular firm to bring the technology to market, there will be a short period in which the technology is vulnerable to traditional countermeasures mediated by attacks on the supporting firm. (If the support is coming from a non-profit institution of some kind this period of vulnerability need not occur.) However, an open source technology will rapidly become independent of any particular firm because as soon as the technology has diffused sufficiently to create a demand that would support other companies with open source business strategies of the kind described in the previous section, other suppliers will step in.

7.3.3 Competitive countermeasures

Thus, once an open source technology appears in the marketplace, players following a proprietary strategy have a limited range of possible responses. The first is to attempt to compete on quality. As noted above, theory suggests that the diffusion of open source depends at least in part on the initial distribution of user beliefs about the intrinsic value of the technology. Thus, if proprietary com-

[34]CAMBIA, BioForge, http://www.bios.net/bioforge, last accessed 22 December 2004.
[35]Bonaccorsi & Rossi (2003), p.1253.
[36]Hrebejk & Boudreau (2001).

petitors can maintain a perception among users that their technology is intrinsically better than the open source version, they can slow or block the diffusion of that version.[37] One way to do this is to invest aggressively in R&D in order to stay ahead in the quality stakes; this is a beneficial outcome for technology users. However, since what matters is the perception of quality rather than actual quality, another possible strategy is to engage in a marketing war, including spreading "fear, uncertainty and doubt" (FUD) about the open source technology. This is a strategy that has been deliberately adopted with some success by incumbent technology owners in the software context;[38] the point for open source biotechnology is that supporters would need to be prepared to develop effective marketing strategies, an area where some in the open source software community feel it should have done better.[39]

A second option is to follow the old adage, "if you can't beat 'em, join 'em". This approach may often make sense for the runners-up among proprietary firms, who may perceive that given a choice between a proprietary monopoly held by another company and an open source level playing field, open source is the lesser of two evils. Existing proprietary players may be quite reluctant to adopt this approach because, apart from the direct effect of reducing lock-in of existing customers, an open source strategy may run contrary to the corporate culture and will probably involve increased technical challenges due to the need to work with open standards to achieve interoperability.[40] One manifestation of this reluctance may be that they move initially to one of the "hybrid" strategies described in the previous section instead of to a full open source approach.[41] However, ultimately it may appear that the only choice given the successful introduction of a non-proprietary tool kit into a particular market is between leading the movement to open source (and incidentally reaping the first-mover advantages described above) or following,[42] and if that is how the situation appears to these firms they may decide to move quickly despite their reluctance.

A third option for firms who cannot see any alternative source of competitive advantage to proprietary exploitation of their version of the technology or for firms who have sufficient market power to try to "beat 'em" instead of "joining 'em" is to lobby for regulatory intervention to block the diffusion of the open source technology. This approach, akin to engaging in a FUD campaign but at a higher level, has been Microsoft's approach in relation to open source software[43] and could be expected to feature prominently in major pharmaceutical

[37]Bonaccorsi & Rossi (2003), pp.1255-1256.

[38]Open Source Initiative, "Halloween I: Open Source Software (New?) Development Methodology", http://www.opensource.org/halloween/halloween1.php#quote4, last accessed 22 December 2004.

[39]Bruce Perens, personal communication.

[40]West (2003), a study of three substantial "runners-up": Apple, IBM and Sun.

[41]Ibid.

[42]Jeppesen (2002), referring specifically to the derivative markets strategy described above at p.213 – but the point applies generally to open source strategies.

[43]West (2003); see also Worthen (2004): "Microsoft is one of the top lobbying shops in the country, [spending] close to $10 million per year on federal-level lobbyists. ... Microsoft has tight

or agribusiness firms' response to an open source biotechnology, especially given their history in relation to other threats to their profit margin, and especially in the intellectual property field.[44] Any open source biotechnology development effort that did not take this factor into account at the outset and find a way to divert possible opposition from major firms (for example, by persuading a group of them to become champions of the development effort or by securing political backing) could be doomed to failure.

Ultimately, unless monopolists succeed in getting governments to intervene to protect the proprietary approach, market forces will determine the final balance of proprietary and non-proprietary technologies in any given market niche. Simulations of the effects of market variables listed above in relation to diffusion of new technologies suggest that the ultimate outcome in the software context will probably be a mixed ecology of proprietary and non-proprietary approaches (in other words, a point of equilibrium between firms following proprietary and non-proprietary strategies will be reached that does not involve total market domination by either approach).[45]

7.3.4 Application to the biotechnology industry

The foregoing discussion is based loosely on developments in the software industry since the introduction of non-proprietary tool kits in the form of open source software packages. The question arises how generalisable this analysis is to the biotechnology context. In principle there seems no reason to expect that these observations would not be applicable in biotechnology; however, some points are worth noting regarding the limits of this analysis. First, it deals only with successful established firms' response to open source, not with the responses of firms that previously pursued proprietary strategies unsuccessfully or new market entrants[46] – which, however, would appear to have less reason to resist the diffusion of open source technologies.

Second, we have not yet made any comment about the scenario in which a newly developed open source technology opens up an entirely new market or taps a hitherto unserved market niche. In such a case, the effect of network externalities associated with openness would be present without the counteracting lock-in factor regarding existing proprietary technologies. This means that if an open source technology ever colonised a new niche it would be very difficult for a proprietary product to compete, because the open source technology would have all the competitive advantages inherent in open source as well as the advan-

links with many of the most powerful and influential shapers of policy at the federal and state level [and over the past five years to 2004] has developed one of the most sophisticated lobbying networks in the country: one that... makes it difficult for anyone to pass technology-related legislation Microsoft opposes. ... Microsoft has lobbied particularly hard against open source, helping kill state bills that advocate for open source in Oregon and Texas."

[44]See generally Drahos & Braithwaite (2002).

[45]Bonaccorsi & Rossi (2003), pp.1255-1256; West (2003).

[46]West (2003).

tages accruing to an established technology. This explains the keen interest in the open source development model displayed by researchers and institutions with a public interest mission who are working to develop new technologies, such as apomixis:[47] an open source approach would be very powerful in that case. It also suggests the possibility that established firms could be interested in helping to develop new technologies on open source terms as a means of ensuring that those technologies will never fall into the hands of their competitors; however, the attitude of such firms will obviously depend on how likely they think it is that they could get there first on their own.

Third, to the extent that the above analysis of the likely impact of open source technologies on industry structure is drawn from observations of the open source software case, it is important to bear in mind that these observations are necessarily limited to a relatively short period of time, and are in effect only a snapshot of industry evolution. Aside from the general dangers of attempting to generalise from a still-emerging process, we are assuming that the particular open source technology development effort in question will be sustained over a long enough period for the various changes described above to take place. While considerable effort has been expended to gather empirical evidence as to how open source projects get started, little attention has been paid to how they wind down. It is possible, however, to offer the following ideas. Recall from chapter 6 (p.144) that in the user innovation literature, open source is a horizontal user innovation network supported by a community. Within that framework, the impact on an industry of the OS approach can be described in terms of the life cycle of a collective invention regime.[48] With the establishment of a profitable industry, technological uncertainty is reduced and the collective invention process may go down any of the following pathways. First, it may continue alongside competitive industry, creating a situation where private R&D co-exists with collective invention, as discussed in this section. Second, the focus of collective invention may shift to new technological opportunities: institutions formed to facilitate collective invention may persist beyond the need for collective invention with respect to a particular technology, but be re-activated with respect to a new technology for another round: this shows the culture of industry has come to accommodate the process. Third, it may break up into a new competitive industry that may or may not prove robust in the long term.

A related point is that the biotechnology and software industries may actually be more similar than they appear because apparently fundamental differences are in fact artefacts of comparing two industries at different stages in their evolution. For example, it has been suggested that one important difference between software development and biotechnology research and development is that, as we saw in chapter 6, biotechnology R&D is generally considered very expensive whereas software development requires nothing but "a laptop, an Internet con-

[47]Charles Spillane, personal communication; Richard Jefferson, personal communication.
[48]Meyer (2003).

nection and a packet of Doritos".[49] It is true that at present, and in some areas of biotechnology research and development, capital costs are significantly higher than in software, and consequently it may be necessary for user-innovators to enlist the help of established firms or other institutions in order to integrate the results of their collaboration into a finished product, or to seek sponsorship to assist with initial technology development. However, one reason software development appears so cheap in this analysis may be that it ignores the costs of building the necessary infrastructure, including developing operating systems, laying fibre-optic cables for fast cheap phone connections and so on; it is possible to ignore these costs only because they are sunk already, whereas in biotechnology huge investments are still to be made – in other words the difference is one of timing in terms of infrastructure development (see section 6.5.2, p.185). According to Hrebejk, "time is on the side of open source. Historically, market economies favor monopolies when infrastructure is needed. Consider the history of AT&T, utilities or railroads in America. But the infrastructure building period ends at some point – and we are rapidly approaching that point in the software industry".[50] In the biotechnology industry, it is still some considerable distance away. For example, the distribution of pharmaceuticals is highly regulated, and large pharmaceutical companies control global distribution networks; there is no public equivalent of the Internet in this context.[51]

7.3.5 A tool kit for biotechnology research and development

At the end of chapter 3 I argued that there is a need in biotechnology research and development for unencumbered, affordable tool kits that would allow prospective users of a technology to modify that technology to meet their own needs, and that we should look to open source technology licensing as a mechanism by which such tool kits have been generated in the software context. If the sequence of developments described in the previous section were to occur in the biotechnology industry, how would they address the problems described in chapter 3?

The answer to this question is that open source biotechnology would be an antidote to the concentration of corporate power and consequent loss of technological diversity in the biotechnology industry, which results in the needs of smaller market segments being ignored: it would enable smaller players in developed and developing countries to perform sophisticated biotechnology research and development in support of their own goals, and at the same time, by reducing costs it would encourage established industry participants to engage with smaller markets. Open source biotechnology would also permit broader and deeper peer review of new technologies, enhancing their robustness and decreasing environmental and public health risks (and hence the market perception of such risks).

[49] Kevin Sweeney, Open Source Biology workshop.
[50] Hrebejk & Boudreau (2001).
[51] Peter Drahos, personal communication.

7.4 Conclusion: seeds of an open source movement in biotechnology

In this chapter I have argued that open source biotechnology is feasible not just as a licensing scheme or development methodology but as a commercialisation strategy that might appeal to some industry participants. Assuming that a sufficiently useful technology or set of technologies can be made available on open source terms, it is possible to envisage a sequence of changes in industry organisation as a result of the adoption of open source strategies by a few players that amounts to a transformation. If such a transformation were to take place, it would resolve the most important structural problems that currently beset the biotechnology industry and diminish the social value of biotechnology research and development.

While it is not possible to predict whether these structural changes will in fact occur, throughout this thesis we have seen positive evidence that some industry participants are starting to move towards an open source approach in biotechnology. Open source bioinformatics is a trivial example in one sense, in that it is merely an instance of open source software development for biotechnology-related applications, but it is significant because it demonstrates that cultural resistance to open source strategies is not absolute in the biotechnology industry; what resistance does exist may be broken down over time as biotechnology research and development comes to rely more and more on computerised modeling and data analysis. Non-profit organisations such as the Molecular Sciences Institute and the Centre for Applications of Molecular Biology in International Agriculture (CAMBIA) are working towards an open source "kernel of functionalities" or meta-tool kit for biotechnology development.[52] Duke University Law School has recently won a multimillion dollar grant to research Open Source Drugs;[53] Human Genome Project scientists at one time considered copyleft-style licensing of sequence data, abandoning this approach only because it was regarded as insufficiently "open" to be acceptable to the research community.[54] The PIPRA licensing initiative first referred to in chapter 3 (p.59) promises to smooth out many practical difficulties in public interest biotechnology licensing and to establish useful licensing precedents; further licensing issues may be resolved by the new "Science Commons" initiative, linked with Creative Commons

[52]Open Source Biology workshop; Molecular Sciences Institute, "Frequently Asked Questions", http://www.molsci.org/Dispatch?action-WebdocWidget:4809-detail=1, last accessed 22 December 2004; CAMBIA, "Biological Innovation for Open Society", http://www.cambia.org/main/opensource.htm, last accessed 22 December 2004.

[53]" 'Open Genomics': Duke University was recently awarded a 5-year, $4.8 million grant, funded by the National Human Genome Research Institute and Department of Energy, to establish the Duke Center for the Study of Public Genomics. As part of this grant, faculty affiliated with Duke Law School's Center for the Study of the Public Domain will be conducting a five-year Open Drug Research project. This major research project will analyze 'open source'-type models of production in biopharmaceutical research and development.": Arti Rai, email communication via Intellectual Property Research Institute of Australia.

[54]Sulston & Ferry (2002), pp.211-213.

at Stanford University.[55] Some of those involved in negotiations for the International Treaty of Plant Genetic Resources have indicated that open source principles should inform the drafting of a standard MTA under the treaty.[56] A network of public sector apomixis researchers have committed in principle to establishing an open source-style licensing scheme;[57] a professor from the Ontario Agricultural College in Guelph, Canada, has drafted a "GPL for plant germplasm".[58] All of these examples demonstrate the continued relevance in biotechnology research and development of Merton's 1957 dictum:

> Science is an activity involving social collaboration and like any other such activity is subject to shifting fortunes. Science as an institution is under threat... . Scientists are now compelled, as they were at the point of re-emergence of science into the modern world, to vindicate the pursuit of science to the rest of society. In order to do this they have had to undergo a process of self appraisal. This has led to a clarification and reaffirmation of the ethos of modern science.[59]

Open source biotechnology is a part of this clarification and reaffirmation.

[55]Creative Commons, "Welcome to Science Commons", http://science.creativecommons.org/, last accessed 22 December 2004.

[56]Susan Bragdon, personal communication.

[57]Charles Spillane, personal communication.

[58]McNaughton (1999).

[59]Merton (1957), pp.38-39:550-551.

Chapter 8

Conclusions

In this thesis I have argued that an open source approach to biotechnology research and development is both desirable and broadly feasible.

The desirability of open source biotechnology was established in chapters 2 to 4. Alluding to the expansion of intellectual property rights in biotechnology-related inventions that has accompanied the commercial biotechnology revolution of the past three decades, chapter 2 highlighted concerns that strengthening intellectual property protection restricts the flow of information necessary to ongoing innovation in this field. According to early sociologists of science, scientific progress – defined by reference to public interest goals – requires that scientists have access to a common fund of knowledge which they are at liberty to use and build upon in accordance with research priorities set by individual scientists working independently. Merton postulated that scientists' incentive to contribute to the common fund on terms that allow others to use and extend those contributions is provided by the existence of a norm of common ownership; intellectual property rights in scientific knowledge are by definition incompatible with this norm and therefore constitute a threat to scientific progress. More recent thinking in the sociology of science highlights the complexity surrounding the norm of common ownership, but does not contradict the fundamental point: that continuing research and development activity requires access to the output of prior research and that this may be compromised by private ownership of scientific information. For example, the "data stream" theory of scientific research emphasises the wide range of strategic considerations that may affect access practices in any given scientific context, but suggests that access restrictions tend to propagate upstream from the point of potential commercialisation back into the research process, resulting in tighter control over the portions of data streams that are believed to be precursors of potentially patentable products.

Proponents of intellectual property rights might argue that such control is useful because it facilitates central co-ordination of research and development: by subjecting independent research initiatives to an overarching agenda, broad intellectual property rights in early-stage technologies can help to avoid wasteful duplication of effort. However, this argument contradicts the view put forward by sociologists of science that co-ordination of scientific activity takes place most efficiently by mutual adjustment of independent initiatives in light of scientists' awareness of others' research output. Moreover, it assumes that the costs of con-

tracting with the owner of the relevant intellectual property will not be so high as to dissipate any efficiency gains that may be associated with centralised control. In fact, recent economic theory suggests that the costs of entering into agreements for rearranging and exercising rights to technological information may often be significant. Strengthening intellectual property rights in relation to uncodified information may be particularly counterproductive because while intellectual property rights may facilitate information exchange via market mechanisms, they are designed to block the flow of information via non-market mechanisms; such mechanisms are more efficient in transferring uncodified information because of the higher transaction costs involved. Uncodified information makes up a substantial portion of technological information in the field of biotechnology, and the importance of non-market mechanisms in facilitating information flow in the biotechnology industry is confirmed by sociological studies of innovative interorganisational networks in this field.

Thus, the discussion in chapter 2 emphasised the importance of information flow to ongoing innovation in biotechnology, given the essentially co-operative and cumulative nature of biotechnology research and development. It also explained in broad theoretical terms the potential of intellectual property rights to hinder such information flow. Chapter 3 began by asking whether the recent proliferation of intellectual property rights in biotechnology has in fact led to research projects being delayed or abandoned in either medical or agricultural biotechnology. In theory, this effect – dubbed "the tragedy of the anticommons" – relies on two prior conditions: fragmented ownership of complementary intellectual assets and high transaction costs associated with the exchange of those assets. Limited available empirical evidence suggests that public sector agricultural biotechnology research and development is plagued by anticommons tragedy, but that private sector activity in agricultural biotechnology continues despite the existence of both prior conditions, as does public and private sector activity in medical biotechnology. However, the same evidence suggests that ongoing innovation in these sectors is sustained only through the adoption of "working solutions" that exacerbate existing structural problems within the industry. In particular, by raising the costs of participating in biotechnology research and development, these mechanisms simultaneously reduce industry participants' incentive to undertake innovative activity directed towards small markets and exclude smaller players, especially in developing countries, who might otherwise be able to conduct research and development to meet their own needs. Meanwhile, the prices of products developed for larger markets are driven up by both increased costs on the supply side and decreased competition on the demand side.

Various solutions to these and other structural problems associated with intellectual property rights in biotechnology have been proposed, each with its own advantages and disadvantages. Chapter 3 proposes an addition to existing options, arguing that provision of an unencumbered, cheap and readily available set of research and development tools (a biotechnology "tool kit") would remove the proximate cause of many structural problems by reducing the costs of participation in biotechnology research and development. Reduced costs of research and

development would free up resources currently devoted to overcoming transaction costs. Apart from reducing waste, this would create the potential for lower prices for end products; make it more worthwhile for profit-seeking firms to serve smaller markets; reduce the number of high social value exchanges never undertaken because their economic value would be eaten up by transaction costs under current conditions; and (by lowering barriers to entry) would increase the pool of potential participants in biotechnology research and development. Raising the number of participants could be expected to lower prices for end products by increasing competition; it would further lower development costs and improve the quality and safety of products by allowing peer review and reducing the opportunities for fraud and self-deception due to conflicts of interest; and it would allow would-be users of the technology whose needs currently go unmet to innovate on their own behalf. Side benefits might include increased consumer acceptance of biotechnology products and stronger defences against bioterrorism.

Such a tool kit could be provided entirely through publicly funded research and development efforts. However, this is unlikely in the present climate and in any case would fail to harness the considerable innovative capacity of the for-profit sector (much of which has been built, indirectly, using public funds). Chapter 4 introduces the concept of open source as an alternative mechanism for establishing a development tool kit with the requisite properties of affordability, availability and freedom from proprietary restrictions. The open source model as it has evolved in software is highly relevant to the intellectual property-related problems in biotechnology described above because it decouples the commercial exploitation of technological innovations from restrictions on access to and use of those innovations. Open source licensing – in particular, copyleft licensing – substitutes ongoing access to leading-edge technologies developed via collaborative methods for licensing income as a reward for innovative activity; open source business strategies involve exploiting complementary markets, for example for support services, in preference to markets for development tools. Thus, if the open source approach could be translated into biotechnology, the creators of existing and future biotechnology research and development tools might be motivated to make those tools available to others as elements of a biotechnology tool kit free of legal encumbrances and at a low cost. Moreover, because an open source development methodology permits many different levels of involvement, the provision of a biotechnology tool kit via open source methods could harness the contributions of diverse actors drawing on a range of funding sources and would therefore avoid placing a disproportionate burden on any single institution or industry sector.

Assuming the desirability of an open source approach to biotechnology research and development, the question arises whether such an approach would be feasible. In order to undertake a systematic assessment of the feasibility of open source biotechnology it was necessary to construct a model of open source that could be applied outside the software context. In common usage, "open source" is a rather loose term that (by my analysis) incorporates three distinct, though related, features: a set of criteria for technology licensing, a characteristic mode

of innovation and an open-ended collection of business strategies. The feasibility of translating these three aspects into the biotechnology context was discussed in chapters 5, 6 and 7 respectively.

Compared with the other two aspects of the open source model, open source licensing is clearly defined: open source software licences may be certified as such according to an official Open Source Definition (OSD). Chapter 5 reports the salient outcomes of a quasi-technical comparison between the ten elements of the OSD and the provisions of a typical biotechnology licence agreement. This comparison showed that although open source biotechnology licensing would pose some technical challenges, these would not be insurmountable. Rather, the main obstacles to implementing open source-style licences in the biotechnology field would be, first, finding the functional – as distinct from legal – equivalents of open source software licensing provisions, and second, persuading biotechnology industry participants that open source licences would be worth adopting. The first obstacle could be overcome by a combination of "model-mongering" (which could draw on the experience of the open source software community as well as other examples such as the Creative Commons initiative) and trial and error. The second would require industry participants to be convinced that the advantages of the other two aspects of open source – the open source mode of innovation and open source business models – would outweigh the disadvantages in relation to other options for exploitation of a specific technology.

These advantages and disadvantages were discussed in chapters 6 and 7. Chapter 6 assessed the feasibility of open source as a mode of innovation in the biotechnology context by reference to a generalised model of open source as a development methodology that emerges from a strand of literature on user innovation generated within the discipline of innovation management. In this analysis, open source is an example of a community-based horizontal user innovation network. Using both hypothetical and concrete examples taken from fieldwork interviews, chapter 6 demonstrated the actual or potential existence of each of the elements of such a network in relation to at least some areas of biotechnology-related innovation. For other areas, specifically those that are particularly capital-intensive at the production and distribution phase, some modification of the open source model might be required. However, such modifications would be unlikely to detract from the range of benefits identified above.

Chapter 7 focussed on the potential for commercial applications of open source biotechnology research and development, again drawing on the user innovation literature, this time as it relates to the implementation of "tool kits for user innovation". The commercial deployment of tool kits for user innovation is not confined to open source software, but has occurred in a range of technology and business contexts; the key difference between open source software and other user innovation tool kits is that the elements of an open source tool kit are not subject to the usual proprietary restrictions on access and use. This means that open source tool kits not only allow users to generate products or technologies that meet their own needs, but also allow user-innovators to have these products or technologies manufactured by someone other than the tool kit supplier. This is

of greater significance in the case of biotechnology than software because in biotechnology there are likely to be more situations in which individual users must rely on manufacturers to carry out production and distribution. In the absence of reach-through rights to the output of tool kit users, commercial manufacturers must rely on other sources of revenue; chapter 7 documents ways in which open source software business strategies could be applied in the biotechnology context. The chapter closes with an extension of the discussion in chapter 4 concerning the potential impact of an open source approach on the organisation of the biotechnology industry as a whole. The conclusion is that although open source biotechnology research and development activities might be peripheral at first, they could become economically significant, even to the point of transforming the industry.

One of the most striking aspects of the comparison in chapters 6 and 7 between a putative open source approach to biotechnology research and development and current industry practice, in biotechnology and elsewhere, is that none of the elements of the open source model is actually new. This makes it easier to envisage the application of open source principles outside the software context, but does it also imply that an open source approach to biotechnology research and development would be unlikely to have much impact? I would argue that it does not – that while there may be nothing particularly radical about any of the component parts of the open source model described in this thesis, the potential ramifications of open source biotechnology *are* radical, both in relation to the development of specific technologies and in terms of overall industry structure. Addressing structural problems in the biotechnology industry could be expected bring the direction of technology development more into line with the demands of social welfare. If successful, open source biotechnology could serve as a model for the implementation of open source principles in other non-software contexts. Further, by offering researchers a means of expressing other-regarding preferences while at the same time meeting development costs, open source biotechnology could have far-reaching effects on the relationship between the scientific community and the rest of society, providing a new mechanism for reconciling scientists' self-interest (including, these days, commercial self-interest) with the public interest in scientific progress (see "Scientific progress and the 'norms of science'", 2.3, p.11).[1]

When I began the research reported in the second half of this thesis, my initial impression was of a collection of unrelated, ad hoc practices and initiatives within the biotechnology industry directed at countering the worst effects of the prevailing proprietary approach to intellectual property management. As the research progressed, however, the imposition of a generalised model of open source on the raw fieldwork data showed how these phenomena could relate to one another and suggested that conditions were ripe for the emergence of an open source movement in biotechnology. Few of the people I spoke with during the fieldwork phase were in a position to perceive this emerging structure, but nearly

[1]Merton (1957), pp.38-39: 550-551.

all were eager to get a sense of how others were dealing with common problems. At first I had been surprised at the willingness of so many scientists, businesspeople and others to talk with me; soon I came to see myself as a kind of messenger going from room to room in a building full of people having essentially the same discussion behind closed doors, reporting – as best I could within the constraints of confidentiality – on the progress of conversations in other rooms and other corridors. Jamie Boyle has written of the potential value of an overarching concept of "the public domain" (similar to that of "the environment") as a means of uniting and thereby energising initiatives opposing the encroachment of intellectual property protection in a range of contexts, even if the term itself can have no definitive meaning.[2] It is possible that a coherent model of open source biotechnology could serve a similar purpose, although it is clear from the text of conversations quoted in chapters 5 to 7 that discussions of open source biotechnology remain, for the most part, highly speculative:

> It is hard to get away from the environment you are in.... [I]n an increasingly rabid climate... of intellectual property possessiveness, you perhaps cannot imagine how you would do better. So it's good to be able to point to individual examples of open source success. But what I envisage is a situation in which everybody moves together bit by bit, recognising that in that way the whole network improves.[3]

Thus, even if the potential for an open source movement in biotechnology is never fully realised, the attempt to articulate a vision of open source in this context still has considerable value.

[2]Boyle (2001).
[3]John Sulston, telephone communication.

Eben Moglen	General Counsel, Free Software Foundation
Lita Nelsen	Director, Technology Licensing Office, Massachusetts Institute of Technology
Richard Nelson	Faculty Fellow, Institute for Social and Economic Research and Policy, Columbia University, New York
Carol Nottenburg	Chief Legal Officer and Director of Intellectual Property, Center for the Application of Molecular Biology to International Agriculture
Glenn Otis Brown	Executive Director, Creative Commons
Neeru Paharia	Assistant Director, Creative Commons
Bruce Perens	Independent software engineer (Co-founder, Open Source Initiative; Primary author, Open Source Definition)
Karl Poetter	Chief Scientific Officer, Genera Biosystems Pty Ltd
Rex Raimond	Mediator, Meridian Institute
Jerome Reichman	Bunyan S. Womble Professor of Law, Duke University
Francisco Reifschneider	Director, Consultative Group on International Agricultural Research
Lawrence Rosen	General Counsel and Secretary, Open Source Initiative
Suzanne Scotchmer	Professor of Economics and Public Policy, University of California at Berkeley
Charles Spillane	Principal Investigator, Department of Biochemistry, University College Cork, Ireland
John Sulston	Former Director, Sanger Centre, Cambridge, United Kingdom
Kevin Sweeney	Trustee, Molecular Sciences Institute and Director of Corporate Finance, Shook, Hardy and Bacon LLP
Antony Taubman	Acting Director, Traditional Knowledge Division, World Intellectual Property Organization
Michael Tiemann	Chief Technical Officer, Red Hat, Inc.
Gary Toennissen	Director, Food Security, Rockefeller Foundation
Fiona Topfer	Division Manager, Life Sciences, ANUTech Pty Ltd
Jennifer Urban	Fellow, Samuelson Law, Technology and Public Policy Clinic,School of Law, University of California at Berkeley
Joachim von Braun	Director General, International Food Policy Research Institute
Stephanie von Gavel	Executive Manager, Graingene
Eric von Hippel	Professor of Management of Technology, Sloan School of Management, Massachusetts Institute of Technology
Brian Wright	Professor of Agricultural and Resource Economics, University of California at Berkeley

Appendix B

Open Source Biology Workshop

The Open Source Biology workshop took place on March 27, 2003 at the Molecular Sciences Institute, Berkeley, California. The workshop was sponsored by the Molecular Sciences Institute and moderated by Lauren Ha and Kevin Sweeney.

Papers

Roger Brent	"Introduction to open source biology"
Janet Hope	"A roadmap for open source biology"
Neeru Parahia	"Experience from open source software and creative arts movements"
Giovanni Ferrara	"State of the biotechnology industry"
Robert Carlson	"Why open source is an interesting model for biology"

Invited participants

Roger Brent	President, Molecular Sciences Institute
Robert Carlson	Research Scientist, Department of Electrical Engineering, University of Washington
Denise Caruso	Executive Director, Hybrid Vigor Institute
Drew Endy (via Internet)	Fellow, Division of Biological Engineering, Department of Biology, Massachusetts Institute of Technology
Giovanni Ferrara	Director, Burrill & Company
Gregory Graff	Director of Research, Bio Economic Research Associates
Lauren Ha	Administrator, Molecular Sciences Institute
Janet Hope	PhD candidate, Australian National University
Tom Kalil	Special Assistant to the Chancellor, University of California at Berkeley (Former Science and Technology adviser to President Clinton)

Invited participants (continued)

Maryanne McCormick	General Counsel, Molecular Sciences Institute
Neeru Pahariah	Assistant Director, Creative Commons
Paul Rabinow	Professor of Anthropology, University of California at Berkeley
David Soergel	Research Fellow, Molecular Sciences Institute
Kevin Sweeney	Director of Corporate Finance, Shook, Hardy and Bacon LLP
Steven Weber	Associate Professor of Political Science, University of California at Berkeley
Brian Wright	Professor of Agricultural and Resource Economics, University of California at Berkeley

Bibliography

Anonymous (2001). 'Last word: Grassroots innovator'. *The Economist Technology Quarterly* pp. 27–28.

Anonymous (2002). 'Overview of the Alliance for Cellular Signaling'. *Nature* **420**:703–706.

K. J. Arrow (1962). 'Economic Welfare and the Allocation of Resources to Invention'. In R. R. Nelson (ed.), *The Rate and Direction of Inventive Activities.* Princeton University Press, Princeton.

R. C. Atkinson, et al. (2003). 'Public Sector Collaboration for Agricultural IP Management'. *Science* **301**(5630):174–5.

J. H. Barton (1997a). 'The Economic and Legal Context of Contemporary Technology Transfer'. In E. Buscaglia, W. Ratliff, & R. Cooter (eds.), *The Law and Economics of Development*, pp. 83–100. JAI Press, Greenwich.

J. H. Barton (1997b). 'Patents and anti-trust: a rethinking in light of patent breadth and sequential innovation'. *Antitrust Law Journal* **65**:449.

J. H. Barton (2000). 'Reforming the patent system'. *Science* **287**:1933–1934.

J. H. Barton (2001). 'Non-obviousness'. In *Conference on the capital, Economics and History of Intellectual Property*. Haas School of Business, Berkeley, California.

J. H. Barton, et al. (1999). 'Intellectual Property Rights in the Developing World: Implications for Agriculture'. Prepared for the Rural Development Department of the World Bank, June 1999.

G. Bassett & N. Suzor (2003). 'Chapter 7: Recent Developments'. In B. Fitzgerald & G. Bassett (eds.), *Legal Issues Relating to Free and Open Source Software*, vol. 1 of *Essays in Technology Policy and Law*, pp. 123–126. Queensland University of Technology School of Law, Brisbane.

B. Behlendorf (1999). 'Open Source as a Business Strategy'. In C. DiBona, S. Ockman, & M. Stone (eds.), *Open Sources: Voices from the Open Source Revolution*, pp. 1–14. O'Reilly, Online version.

Y. Benkler (2002). 'Coase's Penguin, or, Linux and The Nature of the Firm'. *Yale Law Journal* **112**:369.

Y. Benkler (2004). '"Sharing Nicely": On shareable goods and the emergence of sharing as a modality of economic production'. *Yale Law Journal* **114**(273).

A. Bennett, et al. (2002). 'Public Sector Intellectual Property Management for Agricultural Research and Development'. Invited presentation, International Consortium on Agricultural Biotechnology Research, International Conference, Ravello, Italy, July 2002.

E. Birney (2002). 'A case for open source bioinformatics'. In *the O'Reilly bioinformatics technology conference, January 28-31, 2002*, Tucson Arizona. O'Reilly network.

M. Blakeney (2001). 'Intellectual Property Rights and Global Food Security'. *Bioscience Law Review* 4(4):127–140.

D. Blumenthal (1992). 'Academic-Industry Relationships in the Life Sciences'. *Journal of the American Medical Association* **268**(23):3344–3349.

D. Blumenthal, et al. (1997). 'Witholding Research Results in Academic Life Science'. *Journal of the American Medical Association* **277**(15):1224–1228.

D. Blumenthal, et al. (1996a). 'Participation of Life-Science Faculty in Research Relationships with Industry'. *New England Journal of Medicine* **335**(23):1734–1739.

D. Blumenthal, et al. (1996b). 'Relationships between Academic Institutions and Industry in the Life Sciences – an Industry Survey'. *New England Journal of Medicine* **334**(6):368–373.

D. Blumenthal, et al. (1986). 'University-Industry Research Relationships in Biotechnology: Implications for the University'. *Science* **232**:1361–1366.

A. Bonaccorsi & C. Rossi (2003). 'Why open source software can succeed'. *Research Policy* **32**(7):1243–1258.

J. Boyle (2001). 'The Second Enclosure Movement and the Construction of the Public Domain'. In *Conference on the Public Domain*, Duke University School of Law, Durham, North Carolina, November 9-11, 2001. Duke University.

J. Braithwaite & P. Drahos (2000). *Global Business Regulation*. Cambridge University Press, Cambridge.

G. Brennan & P. Pettit (2000). 'The Hidden Economy of Esteem'. *Economics and Philosophy* **16**:77–98.

M. Buchanan (2002). *Small World: Uncovering Nature's Hidden Networks*. Phoenix, London.

R. Bud (1998). 'Molecular Biology and the Long-Term History of Biotechnology'. In A. Thackray (ed.), *Private Science: Biotechnology and the Rise of the Molecular Sciences*, The Chemical Sciences in Society Series, pp. 3–19. University of Pennsylvania Press, Philadelphia.

D. Burk (2002). 'Open Source Genomics'. *Boston University Journal of Science and Technology Law* 8:254. Symposium on Bioinformatics and Intellectual Property Law April 27, 2001, Boston, Mass. (Winter 2002).

W. J. Caelli (2003). 'Chapter 5: Security With Free and Open Source Software'. In B. Fitzgerald & G. Bassett (eds.), *Legal Issues Relating to Free and Open Source Software*, vol. 1 of *Essays in Technology Policy and Law*, pp. 90–115. Queensland University of Technology School of Law, Brisbane.

Calzada, Vieille et al. (1996). 'Apomixis - The Asexual Revolution'. *Science* **274**(5291):1322.

A. Cambrosio & P. Keating (1998). 'Monoclonal Antibodies: From Local to Extended Networks'. In A. Thackray (ed.), *Private Science: Biotechnology and the Rise of the Molecular Sciences*, The Chemical Sciences in Society Series, pp. 165–181. University of Pennsylvania Press, Philadelphia.

E. G. Campbell, et al. (2000). 'Data with holding in academic medicine: characteristics of faculty denied access to research results and biomaterials'. *Research Policy* **29**:303–312.

R. Carlson (2001). *Open Source Biology and its Impact on Industry*. IEEE Spectrum (online magazine of the Institute of Electrical and Electronics Engineers), http://www.spectrum.ieee.org/WEBONLY/resource/may01/spea.html.

A. C. Y. Chang & S. N. Cohen (April 1974). 'Genome Construction Between Bacterial Plasmids In Vitro: Replication and Expression of Staphylococcus Genes in Escherichia Coli'. *Proceedings of the National Academy of Sciences USA* **71**(4):1030–1034.

S. N. Cohen, et al. (November 1973). 'Construction of Biologically Functional Bacterial Plasmids In Vitro'. *Proceedings of the National Academy of Sciences USA* **70**(11):3240–3244.

H. Collins & T. Pinch (1994). *The Golem: What Everyone should know about Science*. Cambridge University Press, Cambridge.

Commission on Intellectual Property Rights (2002). *Integrating Intellectual Property Rights and Development Policy*. November 2002 (2nd Edition).

Council on Governmental Relations (1996). *A Review of University Industry Research Relationships*. March 27.

Council on Governmental Relations (1999). *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations*. March 27.

Council on Governmental Relations (2001). *Materials Transfer in Academia*. March 27.

A. N. H. Creager (1998). 'Biotechnology and Blood: Edwin Cohn's Plasma Fractionation Project, 1940-1953'. In A. Thackray (ed.), *Private Science: Biotechnology and the Rise of the Molecular Sciences*, The Chemical Sciences in Society Series, pp. 39–64. University of Pennsylvania Press, Philadelphia.

K. G. Dau-Schmidt (1997). 'Law and Society & Law and Economics: Common Ground, Irreconcilable Differences, New Directions: Economics and Sociology: The Prospects for an Interdisciplinary Discourse on Law'. *Wisconsin Law Review* **1997**:389–420.

C. DeBresson & F. Amesse (1991). 'Networks of Innovators: A Review and Introduction to the Issue'. *Research Policy* **20**:363–379.

C. DiBona, et al. (eds.) (1999). *Open Sources: Voices from the Open Source Revolution.* O'Reilly, Online version, 1st edn.

B. Douthwaite (2002). *Enabling Innovation.* Zed Books, London.

P. Drahos (1996). *A Philosophy of Intellectual Property.* Dartmouth Series in Applied Legal Philosophy. Dartmouth, Dartmouth.

P. Drahos (2000). 'Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?'. *European Intellectual Property Review* **2000**(6):245–250.

P. Drahos (2002). 'Developing Countries and International Intellectual Property Standard-Setting'. *Journal of World Intellectual Property* **5**:765–789.

P. Drahos & J. Braithwaite (2002). 'Chapter 10: Biogopolies'. In *Information Feudalism: Who Owns the Knowledge Economy?*, pp. 150–168. Earthscan, London.

W. Eamon (1975). 'From the Secrets of Nature to Public Knowledge: the Origins of the Concept of Openness in Science'. *Minerva* **XXIII**(3):321–347.

R. S. Eisenberg (1987). 'Proprietary Rights and the Norms of Science in Biotechnology Research'. *Yale Law Journal* **97**(2):177–231.

R. S. Eisenberg (1989). 'Patents and the Progress of Science: Exclusive Rights and Experimental Use'. *University of Chicago Law Review* **56**:1017–1086.

R. S. Eisenberg (2000). 'Re-examining the role of patents in appropriating the value of DNA sequences'. *Emory Law Journal* **49**(3):783–800.

R. S. Eisenberg (2001). 'Bargaining over the transfer of proprietary research tools: is this market failing or emerging?'. In R. C. Dreyfuss, D. Zimmerman, & H. First (eds.), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, pp. 223–249. Oxford University Press, Oxford.

T. Ellis (2000). 'Distortion of patent economics by litigation costs'. In *Proceedings of the 1999 Summit Conference on Intellectual Property, University of Washington, Seattle.* CASRIP Symposium Publication Series Number 5, http://www.law.washington.edu/casrip/Symposium/Number5/pub5atcl3.pdf.

M. Enserink (1999). 'NIH Proposes Rules for Materials Exchange'. *Science* **284**:1445.

Environment and Production Technology Division and International Food Policy Research Institute (2000). *South-North Trade, Intellectual Property Jurisdictions, and Freedom to Operate in Agricultural Research on Staple Crops.* Discussion paper 70.

Environment and Production Technology Division and International Food Policy Research Institute (2001). *Accessing Other People's Technology: Do Non-profit Agencies Need It? How To Obtain It.* Discussion paper 79.

Ernst&Young (2000). *Convergence: Ernst & Young's Biotechnology Industry Report, Millennium Edition.* Biotechnology industry report.

H. Etzkowitz (1989). 'Entrepreneurial science in the academy: a case of the transformation of norms'. *Social Problems* **36**(1):14–29.

B. Fitzgerald & G. Bassett (2003). 'Chapter 2: Legal Issues Relating to Free and Open Source Software'. In B. Fitzgerald & G. Bassett (eds.), *Legal Issues Relating to Free and Open Source Software*, vol. 1 of *Essays in Technology Policy and Law*, pp. 11–36. Queensland University of Technology School of Law, Brisbane.

J. L. Fox (1981). 'Can academia adapt to biotechnology's lure?'. *Chemical and Engineering News* **October 12, 1981**:39–44.

N. Franke & M. Schreier (2002). 'Entrepreneurial Opportunities with Toolkits for User Innovation and Design'. *The International Journal on Media Management* **Vol. 4**(4):225–235.

N. Franke & S. Shah (2002). 'How Communities Support Innovative Activities: An Exploration of Assistance and Sharing Among End-Users'. Sloan Working Paper #4164, January 2002.

N. Franke & E. von Hippel (2003). 'Satisfying heterogeneous needs via innovation toolkits: the case of Apache security software'. *Research Policy* **32**:1199–1215.

J. H. Fujimura (1987). 'Constructing "Do-able" Problems in Cancer Research: Articulating Alignment'. *Social Studies of Science* **17**:257–293.

R. P. Gabriel & R. Goldman (2004). *Open source: beyond the fairy-tales.* Free/Open Source Research Community online papers collection. http://opensource.mit.edu/papers/gabrielgoldman.pdf, last accessed 22 December 2004.

L. Galambos & J. E. Sewell (1997). *Confronting AIDS: Science and Business Cross a Unique Frontier*. Merck & Co, Inc.

L. Galambos & J. L. Sturchio (1998). 'Pharmaceutical firms and the transition to biotechnology: A study in strategic innovation'. *Business History Review* **72**(2):250.

M. Galanter (1974). 'Why the "Haves" Come Out Ahead: Speculations on the Limits of Legal Change'. *Law and Society Review* **9**:950–997.

M. Galanter & M. A. Edwards (1997). 'Law and Society & Law and Economics: Common Ground, Irreconcilable Differences, New Directions'. *Wisconsin Law Review* **1997**:375–387.

N. Gallini & S. Scotchmer (2002). 'Intellectual Property: When is it the best incentive system?'. In J. Lerner & S. Stern (eds.), *Innovation Policy and the Economy*, vol. 2, pp. 51–78. MIT Press, Boston.

P. Gampe & R. Weatherley (2003). 'Chapter 6: The Developers' Perspective - Commentaries'. In B. Fitzgerald & G. Bassett (eds.), *Legal Issues Relating to Free and Open Source Software*, vol. 1 of *Essays in Technology Policy and Law*, pp. 116–122. Queensland University of Technology School of Law, Brisbane.

G. Graff, et al. (2001). 'Intellectual Property Clearinghouse Mechanisms for Agriculture: Summary of an Industry, Academia, and International Development Round Table'. *IP Strategy Today* **2001**(3):15–38.

G. Graff, et al. (2003a). 'Privatization and innovation in agricultural biotechnology'. *Agriculture and Resource Economics Update* **6**.

G. Graff & D. Zilberman (2001a). 'An intellectual property clearinghouse for agricultural biotechnology'. *Nature Biotechnology* **19**(December):1179–1180.

G. Graff & D. Zilberman (2001b). 'Towards an Intellectual Property Clearinghouse for Agricultural Biotechnology'. *IP Strategy Today* **2001**(3):1–13.

G. D. Graff (2002). 'The Sources of Biological Innovation in Agriculture: Comparative Advantages of Public, Entrepreneurial, and Corporate R&D' Online version, http://are.berkeley.edu/~ggraff/Graff-Sources-dissertation-version.pdf.

G. D. Graff, et al. (2003b). 'Agricultural Biotechnology's Complementary Intellectual Assets'. *Review of Economics and Statistics* **85**(2).

M. Granovetter (1973). 'The Strength of Weak Ties'. *American Journal of Sociology* **78**:1360–80.

G. Hardin (1968). 'Tragedy of the Commons'. *Science* **162**:1243–1248.

D. Harhoff, et al. (2002). 'Profiting from voluntary information spillovers: How users benefit from freely revealing their innovations'. http://userinnovation.mit.edu/papers/3.pdf, last accessed 22 September 2004.

F. Hecker (2000). 'Setting Up Shop: The Business of Open-Source Software'.

M. A. Heller (1998). 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets'. *Harvard Law Review* **111**:621.

M. A. Heller & R. S. Eisenberg (1998). 'Can Patents Deter Innovation? The Anticommons in Biomedical Research'. *Science* **280**(1 May 1998):698–701.

C. Herstatt & E. von Hippel (1992). 'From experience: developing new product concepts via the lead user method: a case study in a "low-tech" field'. *Journal of Product Innovation Management* **1992**(9):213–221.

G. Hertel, et al. (2003). 'Motivation of software developers in open source projects: an internet-based survey of contributors to the Linux kernel'. *Research Policy* **32**(7):1159–1177.

S. Hilgartner (1995). 'Biomolecular Databases: New Communication Regimes for Biology?'. *Science Communication* **17**(2):240–263.

S. Hilgartner (1997). 'Access to Data and Intellectual Property: Scientific Exchange in Genome Research'. In N. R. Council (ed.), *Intellectual Property Rights and Research Tools in Molecular Biology*, pp. 1–9. National Academy Press, Washington, D. C.

S. Hilgartner (1998). 'Data Access Policy in Genome Research'. In A. Thackray (ed.), *Private Science*, The Chemical Sciences in Society Series, pp. 202–218. University of Pennsylvania Press, Pennsylvania.

S. Hilgartner & S. I. Brandt-Rauf (1994). 'Data Access, Ownership, and Control: Toward Empirical Studies of Access Practices'. *Knowledge: Creation, Diffusion, Utilization* **15**(4):355–372.

L. A. Hollaar (2002). *Legal Protection of Digital Information.* BNA Books, http://www.bna.com/bnabooks/.

P. Hrebejk & T. Boudreau (2001). 'The coming "open monopoly" in software' http://news.com.com/The+coming+open+monopoly+in+software/2010-1071_3-281588.html.

T. Hubbard (2003). 'Medicines without barriers: from the human genome project to open development models for medical R&D'. *New Scientist* 14 June.

O. S. Initiative (2002). 'Open Source Case for Business'.

INTECH (1991). *Biotechnology: Generation, Diffusion and Policy, An Interpretive Survey.* Institute for New Technologies, United Nations University.

P. C. J. James (2003). 'Chapter 4: Open Source Software: An Australian Perspective'. In B. Fitzgerald & G. Bassett (eds.), *Legal Issues Relating to Free and Open Source Software,* vol. 1 of *Essays in Technology Policy and Law,* pp. 63–89. Queensland University of Technology School of Law, Brisbane.

L. B. Jeppesen (2002). 'The Implications of "User Toolkits for Innovation"'.

L. B. Jeppesen & M. J. Molin (2003). 'Consumers as co-developers: Learning and innovation outside the firm'.

K. Jordan & M. Lynch (1998). 'The Dissemination, Standardisation and Routinisation of a Molecular Biological Technique'. *Social Studies of Science* **28**:773–800.

L. E. Kay (1998). 'Problematizing Basic Research in Molecular Biology'. In A. Thackray (ed.), *Private Science: Biotechnology and the Rise of the Molecular Sciences,* The Chemical Sciences in Society Series, pp. 20–38. University of Pennsylvania Press, Philadelphia.

G. Keizer (2004). 'Linux To Ring Up $35B By 2008'. *TechWeb News* Dec 16, http://www.informationweek.com/story/showArticle.jhtml ?articleID=55800672.

C. A. Kenwood (2001). *A business case study of open source software.* Report on OSS for U.S. Dept. of Defence, MP 0 1B 0000048, The Mitre Corporation.

D. J. Kevles (1998). 'Diamond v. Chakrabarty and Beyond: The Political Economy of Patenting Life'. In A. Thackray (ed.), *Private Science: Biotechnology and the Rise of the Molecular Sciences,* The Chemical Sciences in Society Series, pp. 65–79. University of Pennsylvania Press, Philadelphia.

E. E. Kim (2003). 'An Introduction to Open Source Communities'. Blue Oxen Associates, http://www.blueoxen.org/research/00007/BOA-00007.pdf.

E. W. Kitch (1977). 'The Nature and Function of the Patent System'. *Journal of Law and Economics* **20**:265–290.

J. Knight (2003). 'Crop Improvement: A Dying Breed'. *Nature* **421**:568–570.

T. S. Kuhn (1970). *The Structure of Scientific Revolutions.* University of Chicago Press, Chicago.

K. Lakhani & E. von Hippel (2002). 'How Open Source Software Works: "Free" User to User Assistance'. *Research Policy* **1451**:1–21.

J. O. Lanjouw & M. Schankerman (2001). 'Characteristics of patent litigation: a window on competition'. *RAND Journal of Economics* **32**(1 (Spring)):1 29–151.

L. Laudan (1982). 'Two Puzzles about Science: reflections on some crises in the philosophy and sociology of science'. *History of Science* **20**:253–268.

J. Lerner (2000). 'Patent policy innovations: a clinical examination'. *Vanderbilt Law Review* **53**(6 (Symposium: "Taking Stock: The Law and Economics of Intellectual Property Rights")):1841–1856.

R. C. Levin (1986). 'A new look at the patent system'. *American Economic Review* **76**(2):200.

S. Levy (1984). *Hackers: Heroes of the computer revolution.* Anchor/Doubleday, New York.

R. C. Lewontin (1993). *The Doctrine of DNA Biology as Ideology.* Penguin Books, London.

C. Long (2000). 'Proprietary rights and why initial allocations matter'. *Emory Law Journal* **49**(3 (Summer)):823–836.

P. L. Loughlan (1998). *Intellectual Property: Creative and Marketing Rights.* LBC Information Services, Sydney.

C. Luthje (2000). *Characteristics of innovating users in a consumer goods field: an empirical study of sport-related product consumers.* MIT Sloan School of management. Working Paper, No. 4331-02.

C. Luthje, et al. (2002). 'The dominant role of "local" information in user innovation: The case of mountain biking'. http://hdl.handle.net/1721.1/1804, last accessed 23 October 2004.

M. Mackenzie, et al. (1990). 'Patents and Free Scientific Information in Biotechnology: Making Monoclonal Antibodies Proprietary'. *Science, Technology, & Human Values* **15**(1):65–83.

T. Mandeville (1996). *Understanding Novelty: Information, Technological Change, and the Patent System.* Ablex, Norwood, New Jersey.

E. Mansfield (1985). 'How Rapidly Does New Industrial Technology Leak Out?'. *Journal of Industrial Economics* **34**:217–223.

E. Marshall (2001). 'Bermuda Rules: Community Spirit, With Teeth'. *Science* **291 (5507)**(16 February 2001):1192.

S. Maurer (2001). 'Inside the Anticommons: Academic Scientists' Struggle to Commercialise Human Mutations Data, 1999-2001'. In *Conference on the capital, Economics and History of Intellectual Property.* Haas School of Business, Berkeley, California.

S. Maurer, et al. (2004). 'Finding Cures for Tropical Disease: Is Open Source the Answer?'. *Public Library of Science: Medicine* August, 2004, available at http://www.cptech.org/ ip/ health/ rnd/ opendevelopment.html, last accessed 22 December 2004.

K. W. McCain (1991). 'Communication, Competition, and Secrecy: the Production and Dissemination of Research-Related Information in Genetics'. *Science, Technology, & Human Values* **16**(4):491–516.

N. McNaughton (1999). 'Sharing Germplasm'. Raven's Eye Consulting, online article, http://www.ravenseyeconsulting.com/raven_articles_commentary.htm.

R. P. Merges (1996). 'Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations'. *California Law Review* **84**:1293.

R. P. Merges (2000). 'Intellectual property rights and the new institutional economics'. *Vanderbilt Law Review* **53**(6):1857–1877. Symposium: "Taking Stock: The Law and Economics of Intellectual Property Rights".

R. P. Merges (2001). 'Institutions for intellectual property transactions: the case of patent pools'. In R. C. Dreyfuss, D. Zimmerman, & H. First (eds.), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society*, pp. 123–165. Oxford University Press, Oxford.

R. P. Merges & R. R. Nelson (1990). 'On the Complex Economics of Patent Scope'. *Columbia Law Review* **90**:888–93.

R. K. Merton (1957). 'The Normative Structure of Science (reprinted from its inclusion in Social Theory and Social Structure, New York, Free Press, pp550-61)'. In H. Nowotny & K. Taschwer (eds.), *The Sociology of the Sciences*, vol. I, pp. 38–49. Edward Elgar Publishing Ltd, Cheltenham.

P. B. Meyer (2003). 'Episodes of Collective Invention'. BLS Working Papers Working Paper 368, U.S. Department of Labor Bureau of Labor Statistics Office of Productivity and Technology.

I. I. Mitroff (1974). 'Norms and Counter-Norms in a Select Group of the Apollo Moon Scientists: A Case Study of the Ambivalence of Scientists'. *American Sociological Review* **39**:579.

E. Moglen (2003). *Questioning SCO: A Hard Look at Nebulous Claims.* http://www.osdl.org/ newsroom/ articles/ ebenmoglenpositionpaper/ redirect_link, last accessed December 21, 2004.

J. Y. Moon & L. Sproull (2001). 'Turning Love into Money: How some firms may profit from voluntary electronic customer communities'. http://userinnovation.mit.edu/papers/Vol-Customers.pdf, last accessed December 22 2003.

M. Morgan (2002). 'Data Release Issues Illustrated by Some Major Public-private Research Consortia'. In *Symposium on the Role of Scientific and Technical Data and Information in the Public Domain*, National Academy of Sciences, Washington DC, 5-6 September 2002. National Academy of Sciences.

P. Morrison, et al. (2002). 'The Nature of Lead Users and Measurement of Leading Edge Status'. http://userinnovation.mit.edu/papers/4.pdf.

J. F. Morrow, et al. (May 1974). 'Replication and Transcription of Eukaryotic DNA in Escherichia Coli'. *Proceedings of the National Academy of Sciences USA* **71**(5):1743–1747.

M. Mulkay (1980). 'Interpretation and the Use of Rules: the Case of the Norms of Science'. *Transactions of the New York Academy of Sciences (Series II)* **39**:111–125.

M. J. Mulkay (1976). 'Norms and ideology in science'. *Sociology of Scientific Information* **15**(4/5):637–656.

A. M. Muniz & T. C. O'Guinn (2001). 'Brand Community'. *JOURNAL OF CONSUMER RESEARCH* **27**:412–432.

National Research Council (1997). *Intellectual Property Rights and Research Tools in Molecular Biology*. National Academy Press, Washington, D.C.

R. Nelson (1990). *What is public and what is private about technology?* Center for Research in Management, University of California at Berkeley, Berkeley CA. Consortium on Competitiveness and Cooperation, Working Paper number 90-9.

R. D. Nelson & R. Mazzoleni (1997). 'Economic Theories About the Costs and Benefits of Patents'. In N. R. Council (ed.), *Intellectual Property Rights and Research Tools in Molecular Biology*, pp. 1–9. National Academy Press, Washington, D. C.

D. Nicol & J. Nielsen (2003). *Patents and medical biotechnology: An empirical analysis of issues facing the Australian industry*. Centre for Law and Genetics Occasional Paper No. 6.

J. Nielsen (2001). 'Biotechnology Patent Licences and Anti-Competitive Conduct'. In *Symposium – Regulating the New Frontiers: Legal Issues in Biotechnology*, Hobart. Centre for Law and Genetics, Faculty of Law, University of Tasmania.

T. Noble (2003). 'Junk DNA Pioneer Defends Patents'. *The Age Newspaper* www.theage.com.au/ articles/ 2003/07/08/ 1057430202587.html.

W. Norhaus (1969). *Invention, Growth, and Welfare: A Theoretical Treatment of Technological Change*. MIT Press, Cambridge, Mass.

C. Nottenburg, et al. (2002). 'Accessing Other People's Technology for Non-Profit Research'. *Australian Journal of Agricultural and Resource Economics* **46**(3):389–416.

H. Nowotny & K. Taschwer (eds.) (1996). *The Sociology of the Sciences.* Edward Elgar Publishing Ltd, Cheltenham.

A. Nuvolari (2001). 'Collective Invention during the British Industrial Revolution: The Case of the Cornish Pumping Engine'. http://fp.tm.tue.nl/ecis/Workingaccessed 22 December 2004.

S. O'Mahony (2003). 'Guarding the commons: how community managed software projects protect their work'. *Research Policy* **32**(7):1179–1198.

G. O'Neill (2003). 'Coming soon: The DIY plant biotech kit'. *Australian Biotechnology News* , http://www.geneticsmedia.org/ABN/2003 - June 6.pdf.

D. W. Opderbeck (2004). 'The penguin's genome, or Coase and open source biotechnology'. Available at http://ssrn.com/abstract=574804, last accessed 22 December 2004.

M. O'Rourke (2000). 'Toward a doctrine of fair use in patent law'. *Columbia Law Review* **100**(June 2000):1177–1250.

E. Ostrom (1990). *Governing the Commons: The Evolution of Institutions for Collective Action.* Cambridge University Press, New York.

J. Owen-Smith & W. W. Powell (2001). *Careers and Contradictions: Faculty Responses to the Transformation of Knowledge and its Uses in the Life Sciences.* Forthcoming in volume 10 *Research in the Sociology of Work.*

B. Perens (1999). 'The Open Source Definition'. In C. DiBona, S. Ockman, & M. Stone (eds.), *Open Sources: Voices from the Open Source Revolution,* pp. 1–11. O'Reilly, Online version.

M. Polyani (1958). *Personal Knowledge: Towards a Post-Critical Philosophy.* University of Chicago Press, Chicago Il.

M. Porter (2001). 'Strategy and the Internet'. *Harvard Business Review* **79**(3):63–80.

W. W. Powell (2001). 'Networks of Learning in Biotechnology: Opportunities and Constraints associated with Relational Contracting in a Knowledge-Intensive Field'. In R. C. Dreyfuss, D. Zimmerman, & H. First (eds.), *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society,* pp. 251–266. Oxford University Press, Oxford.

C. E. Pray & A. Naseem (2003). *The Economics of Agricultural Biotechnology Research.* ESA Working Paper No. 03-07, www.fao.org/ es/ ESA/ pdf/ wp/ ESAWP03_07.pdf, last accessed 20 May 2004.

A. Rai (2003). 'Collective Action and Technology Transfer: The Case of "Low-Value" Research'. In *Conference on International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime, April 4 - 6, 2003, Duke Law School, Durham, North Carolina*, http://www.law.duke.edu/trips/ webcast.html.

A. K. Rai & R. S. Eisenberg (2003). 'Bayh-Dole Reform and the Progress of Biomedicine'. *Law and Contemporary Problems* **66**(Winter/Spring):289.

E. S. Raymond (1999). 'A Brief History of Hackerdom'. In C. DiBona, S. Ockman, & M. Stone (eds.), *Open Sources: Voices from the Open Source Revolution*, pp. 1–7. O'Reilly, Online version.

E. S. Raymond (2001). *The Cathedral and the Bazaar: Musings on Linux and Open Source by an Accidental Revolutionary*, vol. 2001. O'Reilly, Online version.

P. J. Regal (1996). 'Metaphysics in Genetic Engineering: Cryptic Philosophy and Ideology in the "Science" of Risk Assessment'. In A. V. Dommelen (ed.), *Coping with Deliberate Release: the Limits of Risk Assessment*. International Centre for Human and Public Affairs, Tilburg/Buenos Aires.

J. H. Reichman & P. F. Uhlir (2002). 'Promoting Public Good Uses of Scientific Data: A Contractually Reconstructed Commons for Science and Innovation'. Retrieved September 22, 2004 from http://www.law.duke.edu/pd /papers/ReichmanandUhlir.pdf.

S. Ricketson & M. Richardson (1998). *Intellectual Property Cases, Materials and Commentary*. Butterworths, Sydney, 2 edn.

C. Roa-Rodriguez & C. Nottenburg (2004). *Agrobacterium-mediated transformation of plants, version 3 (July 2003)*. Cambia White Paper, http:// www.bios.net/ uploads/ images/ 9/ AMT.pdf, last accessed 17 December 2004.

L. Rosen, et al. (2003). 'Chapter 3: Live From Silicon Valley, Views of Open Source Practitioners'. In B. Fitzgerald & G. Bassett (eds.), *Legal Issues Relating to Free and Open Source Software*, vol. 1 of *Essays in Technology Policy and Law*, pp. 37–62. Queensland University of Technology School of Law, Brisbane.

N. Rosenberg (1982). *Inside the Black Box: Technology and Economics*. Cambridge University Press, New York.

Royal Commission on Genetic Modification (2001). 'Report of the Royal Commission on Genetic Modification' Accessed via http:// www.mfe.govt.nz/ publications/organisms/royal-commission-gm/index.html.

P. Samuelson (2001). 'Digital Information, Digital Networks, and the Public Domain'. In *Conference on the Public Domain*, Duke University School of Law, Durham, North Carolina, November 9-11, 2001. Duke University.

Scientific Working Group on Biosafety (1998). *Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms.* The Edmonds Institute, http://www.edmonds-institute.org/manual.html, last accessed 21 December 2004.

S. Scotchmer (1991). 'Standing on the Shoulders of Giants: Cumulative Research and the Patent Law'. *Journal of Economic Perspectives* 5(1):29–41.

S. Scotchmer (1999). *Cumulative Innovation in Theory and Practice. Goldman School of Public Policy Working Paper 240.* University of California (Berkeley), Berkeley.

A. Silverman (1995). 'The Relationship Between Basic and Improvement Patents'. *Journal of Minerals, Metals & Materials* 47(1):50.

Simputer Trust (2004). Web site, http://www.simputer.org/simputer/, last accessed 29 October 2004.

J. S. Smith (1990). *Patenting the Sun: Polio and the Salk Vaccine.* William Morrow & Co., New York.

J. Spolsky (2004). 'Platforms' http://sss.joelonsoftware.com/ articles/ Platforms.htm, last accessed June 22 2004.

R. M. Stallman (1999). 'The GNU Operating System and the Free Software Movement'. In C. DiBona, S. Ockman, & M. Stone (eds.), *Open Sources: Voices from the Open Source Revolution,* pp. 1–12. O'Reilly, Online version.

J. Straus, et al. (2002). 'Empirical Survey on "Genetic Inventions and Patent Law"'. Published at the OECD expert workshop on Genetic Inventions, Intellectual Property Rights and Licensing Practices, Berlin 2002.

J. Sulston & G. Ferry (2002). *The Common Thread.* Random House, London.

C. R. Sunstein (1996). 'Social Norms and Social Roles'. *Columbia Law Review* 96:903.

A. Thackray (ed.) (1998). *Private Science: Biotechnology and the Rise of the Molecular Sciences.* University of Pennsylvania Press, Philadelphia.

The Molecular Sciences Institute (2004). FAQs http://www.molsci.org/ Dispatch? action-WebdocWidget:4809-detail=1.

N. Thompson (2002). 'May the Source Be With You'. *The Washington Monthly Online* **July/August 2002**:1–5.

A. Thro & C. Spillane (2000). *Biotechnology-Assisted Plant Breeding: Complement or Contradiction.* CGIAR Systemwide Program on Participatory Research & Gender Anlaysis for Technology Development and Institutional Innovation. Working Document No. 4.

M. Tiemann (1999). 'Future of Cygnus Solutions: An Entrepreneur's Account'. In C. DiBona, S. Ockman, & M. Stone (eds.), *Open Sources: Voices from the Open Source Revolution*, pp. 1–12. O'Reilly, Online version.

S. von Gavel (2001). 'Biotechnology Licensing'. In *Licensing Course 2001*, Leuven-Belgium, 13-14 December 2001.

E. von Hippel (1988). *Sources of Innovation*. Oxford University Press, Oxford.

E. von Hippel (1994). '"Sticky Information" and the Locus of Problem Solving: Implications for Innovation'. *Management Science* **40**(4):429–439.

E. von Hippel (2002). 'Horizontal Innovation Networks - by and for Users'. http://opensource.mit.edu/papers/vonhippel3.pdf, last accessed 22 December 2004.

E. von Hippel & R. Katz (2002). 'Shifting innovation to users via toolkits'. *Management Science* **48**(7):821–834.

E. von Hippel & G. von Krogh (2001). 'Open Source Software and a "Private-Collective" Innovation Model: Issues for Organization Science'. http://opensource.mit.edu/papers/hippelkrogh.pdf, last accessed 22 December 2004.

G. von Krogh, et al. (2003). 'Community, joining, and specialization in open source software innovation: a case study'. *Research Policy* **32**(7):1217–1241.

G. von Krogh & E. von Hippel (2003). 'Special issue on open source software development'. *Research Policy* **32**(7):1149–1157.

J. P. A. Walsh & Cohen (2003). 'Effects of Research Tool Patents and Licensing on Biomedical Innovation'. In W. M. C. . S. A. Merrill (ed.), *Patents in the Knowledge-Based Economy*, pp. 285–340. National Academies Press.

M. Ward (2001). 'Indian handheld to tackle digital divide'. *BBC News Online (Science and Technology), Wednesday 18 July* pp. http://news.bbc.co.uk/1/hi/sci/tech/1442000.stm, last accessed 29 October 2004.

M. H. Webbink (2003). 'Chapter 1: Licensing and Open Source'. In B. Fitzgerald & G. Bassett (eds.), *Legal Issues Relating to Free and Open Source Software*, vol. 1 of *Essays in Technology Policy and Law*, pp. 1–10. Queensland University of Technology School of Law, Brisbane.

S. Weber (2004). *The Success of Open Source*. Harvard University Press, Cambridge, Mass.

J. West (2003). 'How open is open enough? Melding proprietary and open source platform strategies'. *Research Policy* **32**(7):1259–1285.

S. Williams (2002). *Free as in Freedom: Richard Stallman's Crusade for Free Software.* O'Reilly.

World Intellectual Property Organization (1992). *Guide to the Licensing of Biotechnology.* WIPO Publication No. 708(E), Geneva.

B. Worthen (2004). 'Mr Gates goes to Washington' sept 15 issue of CIO Magazine, http://www.cio.com/archive/091504/microsoft.html.

B. D. Wright (1998a). 'Public germplasm development at a crossroads: Biotechnology and intellectual property'. *California Agriculture* **52**(6):8–13.

S. Wright (1998b). 'Molecular Politics in a Global Economy'. In A. Thackray (ed.), *Private Science: Biotechnology and the Rise of the Molecular Sciences,* The Chemical Sciences in Society Series, pp. 80–104. University of Pennsylvania Press, Philadelphia.

R. Young (1999). 'Giving It Away: How Red Hat Software Stumbled Across a New Economic Model and Helped Improve an Industry'. In C. DiBona, S. Ockman, & M. Stone (eds.), *Open Sources: Voices from the Open Source Revolution,* pp. 1–8. O'Reilly, Online version.